

**CLINICAL RESEARCH IN INFECTIOUS DISEASES**

**SAFETY SUMMARY REPORT**

**Prepared for DMID Protocol 20-0003:**

**Phase I, Open-Label, Dose-Ranging Study of the Safety and  
Immunogenicity of 2019-nCoV Vaccine (mRNA-1273) in Healthy  
Adults**

**26 OCTOBER 2020**

Prepared and distributed by:  
Statistical and Data Coordinating Center (SDCC)  
Emmes  
Rockville, Maryland

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## TABLE OF CONTENTS

|     |  |    |
|-----|--|----|
| 1.  | SUMMARY .....  | 1  |
| 2.  | PURPOSE OF THE REPORT .....  | 1  |
| 3.  | REVIEW OF THE STUDY DESIGN .....   | 1  |
| 4.  | METHODS FOR SAFETY ASSESSMENTS .....   | 3  |
| 5.  | REVIEW OF THE SAFETY DATA .....  | 3  |
| 5.1 | Overview .....   | 3  |
| 5.2 | Study Status .....   | 4  |
| 5.3 | Halting Rules Surveillance .....   | 5  |
|     | TABLE 1: Study Halting Rules .....   | 5  |
| 5.4 | Adverse Events .....   | 6  |
| 5.5 | Solicited Events and Symptoms.....   | 9  |
| 5.6 | Clinical Laboratory Results and Vital Signs.....   | 12 |
| 5.7 | Protocol Adherence.....  | 13 |
| 5.8 | Pregnancies .....  | 14 |
| 6.  | TABLES AND FIGURES.....  | 14 |
|     | TABLE 2A: Summary of Categorical Demographic and Baseline Characteristics by Vaccination Group -<br>All Subjects 18-55 Years of Age .....  | 15 |
|     | TABLE 2B: Summary of Categorical Demographic and Baseline Characteristics by Vaccination Group -<br>All Subjects 56-70 Years of Age .....  | 16 |
|     | TABLE 2C: Summary of Categorical Demographic and Baseline Characteristics by Vaccination Group -<br>All Subjects ≥71 Years of Age .....  | 17 |
|     | TABLE 2D: Summary of Continuous Demographic and Baseline Characteristics by Vaccination Group -<br>All Subjects 18-55 Years of Age .....   | 18 |
|     | TABLE 2E: Summary of Continuous Demographic and Baseline Characteristics by Vaccination Group -<br>All Subjects 56-70 Years of Age .....   | 19 |
|     | TABLE 2F: Summary of Continuous Demographic and Baseline Characteristics by Vaccination Group -<br>All Subjects ≥71 Years of Age .....   | 20 |
|     | TABLE 2G: Study Status: Number of Subjects Completing Study Milestones .....   | 21 |
|     | TABLE 2H: Subject Disposition Vaccination Group - All Subjects 18-55 Years of Age .....  | 23 |
|     | TABLE 2I: Subject Disposition Vaccination Group - All Subjects 56-70 Years of Age .....  | 24 |
|     | TABLE 2J: Subject Disposition Vaccination Group - All Subjects ≥ 71 Years of Age .....   | 25 |
|     | TABLE 2K: Early Terminations or Discontinued Subjects .....  | 26 |
|     | TABLE 3A: Listing of Serious Adverse Events .....  | 27 |
|     | TABLE 3B: Listing of MAAEs and NOCMCs .....  | 28 |
|     | TABLE 4A(i): Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and<br>Preferred Term, Severity, Relationship, and Vaccination Group – 25 mcg mRNA-1273 18-<br>55 years (N=15) .....  | 32 |
|     | TABLE 4A(ii): Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and<br>Preferred Term, Severity, Relationship, and Vaccination Group – 50 mcg mRNA-1273 18-<br>55 years (N=15) ..... | 34 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE OF CONTENTS** *(continued)*

|   |    |
|---|----|
| TABLE 4A(iii): Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 100 mcg mRNA-1273 18-55 years (N=15) .....                                     | 36 |
| TABLE 4A(iv): Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 250 mcg mRNA-1273 18-55 years (N=15) .....                                      | 38 |
| TABLE 4A(v): Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – mRNA-1273 All Subjects 18-55 years (N=60).....                                   | 41 |
| TABLE 4B(i): Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 25 mcg mRNA-1273 56-70 years (N=10) .....  | 46 |
| TABLE 4B(ii): Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 50 µg mRNA-1273 56-70 years (N=10) .....  | 47 |
| TABLE 4B(iii): Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 100 mcg mRNA-1273 56-70 years (N=10) .....                                     | 48 |
| TABLE 4B(iv): Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 56-70 years (N=30) .....  | 49 |
| TABLE 4C(i): Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 25 mcg mRNA-1273 ≥71 years (N=10) .....  | 51 |
| TABLE 4C(ii): Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 50 mcg mRNA-1273 ≥71 years (N=10) .....   | 53 |
| TABLE 4C(iii): Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 100 mcg mRNA-1273 ≥71 years (N=10) .....                                       | 54 |
| TABLE 4C(iv): Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – ≥71 years (N=30) .....  | 56 |
| TABLE 4D(i): Number and Percentage of Subjects Experiencing Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 25 mcg mRNA-1273 18-55 Years of Age (N=15) ..... | 59 |
| TABLE 4D(ii): Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 50 mcg mRNA-1273 18-55 years (N=15) .....          | 61 |
| TABLE 4D(iii): Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 100 mcg mRNA-1273 18-55 years (N=15) .....        | 63 |
| TABLE 4D(iv): Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 250 mcg mRNA-1273 18-55 years (N=15) .....         | 65 |
| TABLE 4D(v): Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 18-55 years (N=60).....                             | 68 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE OF CONTENTS** *(continued)*

|  |     |
|--|-----|
| TABLE 4E(i): Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 25 mcg mRNA-1273 56-70 years (N=10) .....    | 74  |
| TABLE 4E(ii): Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 50 mcg mRNA-1273 56-70 years (N=10) .....   | 75  |
| TABLE 4E(iii): Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 100 mcg mRNA-1273 56-70 years (N=10) ..... | 76  |
| TABLE 4E(iv): Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 56-70 years (N=30).....                     | 77  |
| TABLE 4F(i): Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 25 mcg mRNA-1273 ≥71 years (N=10) .....      | 80  |
| TABLE 4F(ii): Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 50 mcg mRNA-1273 ≥71 years (N=10) .....     | 82  |
| TABLE 4F(iii): Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 100 mcg mRNA-1273 ≥71 years (N=10) .....   | 83  |
| TABLE 4F(iv): Number and Percentage of Subjects Experiencing Unsolicited Adverse Events MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – ≥71 years (N=30).....                       | 85  |
| FIGURE 1A(i): Maximum Severity of Solicited Events by Symptom and Vaccination Group - Systemic - 18-55 Years of Age.....   | 88  |
| FIGURE 1A(ii): Maximum Severity of Solicited Events by Symptom and Vaccination Group – Local - 18-55 Years of Age.....   | 89  |
| FIGURE 1B(i): Maximum Severity of Solicited Events by Symptom and Vaccination Group - Systemic - 56-70 Years of Age.....   | 90  |
| FIGURE 1B(ii): Maximum Severity of Solicited Events by Symptom and Vaccination Group - Local - 56-70 Years of Age .....  | 91  |
| FIGURE 1C(i): Maximum Severity of Solicited Events by Symptom and Vaccination Group - Systemic - ≥71 Years of Age.....   | 92  |
| FIGURE 1C(ii): Maximum Severity of Solicited Events by Symptom and Vaccination Group - Local - ≥71 Years of Age .....  | 93  |
| TABLE 5A(i): Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group - Any Symptom - 18-55 Years of Age .....  | 94  |
| TABLE 5A(ii): Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Systemic Symptoms - 18-55 Years of Age.....  | 95  |
| TABLE 5A(iii): Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Local Symptoms - 18-55 Years of Age .....   | 100 |



**TABLE OF CONTENTS** *(continued)*

|   |     |
|---|-----|
| TABLE 5B(i): Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Any Symptom - 56-70 Years of Age.....            | 104 |
| TABLE 5B(ii): Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Systemic Symptoms - 56-70 Years of Age.....     | 105 |
| TABLE 5B(iii): Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Local Symptoms - 56-70 Years of Age.....       | 110 |
| TABLE 5C(i): Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Any Symptom - $\geq 71$ years of Age.....        | 114 |
| TABLE 5C(ii): Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Systemic Symptoms - $\geq 71$ years of Age..... | 115 |
| TABLE 5C(iii): Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Local Symptoms - $\geq 71$ years of Age.....   | 120 |
| FIGURE 2A(i): Maximum Severity of Solicited Systemic Symptoms by Days Post Vaccination and Vaccination Group - 18-55 Years of Age .....   | 124 |
| FIGURE 2A(ii): Maximum Severity of Solicited Systemic Symptoms by Days Post Vaccination and Vaccination Group – 56-70 Years of Age .....  | 125 |
| FIGURE 2A(iii): Maximum Severity of Solicited Systemic Symptoms by Days Post Vaccination and Vaccination Group - $\geq 71$ Years of Age .....   | 126 |
| FIGURE 3A(i): Maximum Severity of Solicited Local Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age .....  | 127 |
| FIGURE 3A(ii): Maximum Severity of Solicited Local Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age .....   | 128 |
| FIGURE 3A(iii): Maximum Severity of Solicited Local Symptoms by Days Post Vaccination and Vaccination Group $\geq 71$ Years of Age.....   | 129 |
| FIGURE 4A(i): Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age - Arthralgia.....  | 130 |
| FIGURE 4A(ii): Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age - Arthralgia.....   | 131 |
| FIGURE 4A(iii): Solicited Symptoms by Days Post Vaccination and Vaccination Group $\geq 71$ Years of Age – Arthralgia .....   | 132 |
| FIGURE 4B(i): Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age - Chills .....   | 133 |
| FIGURE 4B(ii): Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age - Chills.....   | 134 |
| FIGURE 4B(iii): Solicited Symptoms by Days Post Vaccination and Vaccination Group $\geq 71$ Years of Age – Chills.....  | 135 |
| FIGURE 4C(i): Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age - Erythema .....   | 136 |
| FIGURE 4C(ii): Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age - Erythema.....   | 137 |

**TABLE OF CONTENTS** *(continued)*

|  |     |
|--|-----|
| FIGURE 4C(iii): Solicited Symptoms by Days Post Vaccination and Vaccination Group $\geq 71$ Years of Age<br>– Erythema .....       | 138 |
| FIGURE 4D(i): Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of<br>Age – Erythema (mm) .....        | 139 |
| FIGURE 4D(ii): Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of<br>Age – Erythema (mm) .....       | 140 |
| FIGURE 4D(iii): Solicited Symptoms by Days Post Vaccination and Vaccination Group $\geq 71$ Years of<br>Age – Erythema (mm) .....  | 141 |
| FIGURE 4E(i): Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age<br>– Fatigue .....              | 142 |
| FIGURE 4E(ii): Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of<br>Age – Fatigue .....             | 143 |
| FIGURE 4E(iii): Solicited Symptoms by Days Post Vaccination and Vaccination Group $\geq 71$ Years of Age<br>– Fatigue .....        | 144 |
| FIGURE 4F(i): Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age<br>– Fever.....                 | 145 |
| FIGURE 4F(ii): Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of<br>Age – Fever .....               | 146 |
| FIGURE 4F(iii): Solicited Symptoms by Days Post Vaccination and Vaccination Group $\geq 71$ Years of Age<br>– Fever .....          | 147 |
| FIGURE 4G(i): Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of<br>Age – Headache.....              | 148 |
| FIGURE 4G(ii): Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of<br>Age – Headache.....             | 149 |
| FIGURE 4G(iii): Solicited Symptoms by Days Post Vaccination and Vaccination Group $\geq 71$ Years of<br>Age – Headache.....        | 150 |
| FIGURE 4H(i): Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of<br>Age – Induration.....            | 151 |
| FIGURE 4H(ii): Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of<br>Age – Induration.....           | 152 |
| FIGURE 4H(iii): Solicited Symptoms by Days Post Vaccination and Vaccination Group $\geq 71$ Years of<br>Age – Induration.....      | 153 |
| FIGURE 4I(i): Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age<br>– Induration (mm).....       | 154 |
| FIGURE 4I(ii): Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age<br>– Induration (mm).....      | 155 |
| FIGURE 4I(iii): Solicited Symptoms by Days Post Vaccination and Vaccination Group $\geq 71$ Years of Age<br>– Induration (mm)..... | 156 |
| FIGURE 4J(i): Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age<br>– Myalgia.....               | 157 |
| FIGURE 4J(ii): Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age<br>– Myalgia.....              | 158 |

**TABLE OF CONTENTS** *(continued)*

|  |     |
|--|-----|
| FIGURE 4J(iii): Solicited Symptoms by Days Post Vaccination and Vaccination Group $\geq 71$ Years of Age – Myalgia ..... | 159 |
| FIGURE 4K(i): Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age - Nausea.....         | 160 |
| FIGURE 4K(ii): Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age - Nausea.....        | 161 |
| FIGURE 4K(iii): Solicited Symptoms by Days Post Vaccination and Vaccination Group $\geq 71$ Years of Age – Nausea.....   | 162 |
| FIGURE 4L(i): Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age - Pain.....           | 163 |
| FIGURE 4L(ii): Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age - Pain .....         | 164 |
| FIGURE 4L(iii): Solicited Symptoms by Days Post Vaccination and Vaccination Group $\geq 71$ Years of Age – Pain .....    | 165 |
| TABLE 6A: Summary of Duration of Solicited Symptoms by Vaccination Group - All Subjects 18-55 Years of Age .....         | 166 |
| TABLE 6B: Summary of Duration of Solicited Symptoms by Vaccination Group - All Subjects 56-70 Years of Age .....         | 171 |
| TABLE 6C: Summary of Duration of Solicited Symptoms by Vaccination Group - All Subjects $\geq 71$ Years of Age .....     | 176 |
| TABLE 7A: Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group - Any Hematology Parameter .....   | 181 |
| TABLE 7B: Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – White Blood Cells .....          | 186 |
| TABLE 7C: Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Hemoglobin .....                 | 191 |
| TABLE 7D: Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Platelets.....                   | 195 |
| TABLE 7E: Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Any Chemistry Parameter.....     | 199 |
| TABLE 7F: Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Alanine Aminotransferase .....   | 203 |
| TABLE 7G: Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Aspartate Aminotransferase ..... | 207 |
| TABLE 7H: Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Alkaline Phosphatase.....        | 211 |
| TABLE 7I: Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Total Bilirubin.....             | 215 |
| TABLE 7J: Laboratory Results by Parameter, Severity, and Study Day Serum Creatinine .....                                | 219 |
| TABLE 7K: Laboratory Results by Parameter, Severity, and Study Day Serum Lipase.....                                     | 223 |
| FIGURE 5A: Clinical Laboratory Results by Severity and Vaccination Group 18-55 Years of Age.....                         | 227 |
| FIGURE 5B: Clinical Laboratory Results by Severity and Vaccination Group 56-70 Years of Age.....                         | 228 |

**TABLE OF CONTENTS** *(continued)*

FIGURE 5C: Clinical Laboratory Results by Severity and Vaccination Group  $\geq 71$  Years of Age .....229

TABLE 8A: Distribution of Protocol Deviations by Category, Type, and Vaccination Group 18-55 Years  
 of Age .....230

TABLE 8B: Distribution of Protocol Deviations by Category, Type, and Vaccination Group 56-70 Years  
 of Age .....231

TABLE 8C: Distribution of Protocol Deviations by Category, Type, and Vaccination Group  $\geq 71$  Years of  
 Age.....232

### **Notes on this Report**

The following notes are provided for clarification of the data included in this safety report:

- Study accrual and vaccinations are complete at the time of this report.
- Data entry, querying, and monitoring are in progress at the time of the report. The data are neither clean nor complete.
- At the time of the data cutoff for this report, 07 October 2020, there were no SAEs reported.
- Appendices are presented in a separate file named:  
[20-0003\\_Safety\\_Summary\\_Report\\_OCT2020\\_appendices.pdf](#).

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

-viii-

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## **SAFETY SUMMARY REPORT**

### **DMID Protocol 20-0003**

Phase I, Open-Label, Dose-Ranging Study of the Safety and Immunogenicity of 2019-nCoV Vaccine (mRNA-1273) in Healthy Adults

#### **1. SUMMARY**

DMID Protocol 20-0003 is examining the safety and immunogenicity of a SARS-CoV-2 vaccine (mRNA-1273 manufactured by ModernaTX, Inc.), for the prevention of 2019-nCoV (SARS-CoV-2) infection. Males and non-pregnant females, 18-55, 56-70, and  $\geq 71$  years old, inclusive, who are in good health and meet all eligibility criteria will receive 2 doses (Days 1 and 29) of mRNA-1273 at 25  $\mu\text{g}$ , 50  $\mu\text{g}$ , 100  $\mu\text{g}$  or 250  $\mu\text{g}$ .

As of the data cutoff date of October 7, 2020, a total of 120 subjects had been enrolled into this study, and vaccination records had been submitted for all 120 subjects for the first dose of vaccine; 116 of these 120 subjects had received the second dose of vaccine; four subjects were discontinued from further vaccinations following their first dose (3 due to AEs and one due to potential COVID-19 exposure). The safety data presented in this report focus on both solicited and unsolicited events experienced by subjects following vaccination and entered in the study database as of the data cutoff date for this report.

#### **2. PURPOSE OF THE REPORT**

This report provides an interim update on the study of 120 subjects enrolled and vaccinated with a data cutoff of October 7, 2020.

#### **3. REVIEW OF THE STUDY DESIGN**

This is a Phase 1, dose-ranging, open-label, sequential study comparing the immunogenicity and safety of SARS-CoV-2 mRNA-1273 vaccine in subjects receiving 2 doses (Days 1 and 29) at 25  $\mu\text{g}$ , 50  $\mu\text{g}$ , 100  $\mu\text{g}$  and 250  $\mu\text{g}$ .

Potential subjects will be screened by medical history, physical exam, vital signs, and clinical laboratory tests including white blood cells (WBC), hemoglobin (Hgb), platelet count, total bilirubin, alanine aminotransferase (ALT), Aspartate aminotransferase (AST), serum lipase, Alkaline Phosphatase (ALP), Prothrombin time (PT), Partial thromboplastin time (PTT), and creatinine (Cr). Height and weight will be obtained to calculate BMI. Urine will be collected for drug screening. Potential female subjects of childbearing potential will have a serum pregnancy test. In addition, potential subjects will be screened for HIV 1 and 2 antibody, Hepatitis C antibody, and Hepatitis B surface antigen prior to study product administration.

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

For this report 120 subjects were enrolled into one of ten cohorts as shown below. Not shown in the table below are cohorts 6 (56 - 70 years old, 250 µg mRNA-1273), 9 ( $\geq 71$  years old, 250 µg mRNA-1273), and 13 (18 - 55 years old, 10 µg mRNA-1273), which the study team decided not to enroll; these cohorts would have enrolled an additional 10, 10, and 15 subjects, respectively. Subjects received an IM injection of mRNA-1273 on Days 1 and 29 in the deltoid and will be followed through 1-year post 2<sup>nd</sup> vaccination (Day 394). The second dose of vaccine (0.5 mL) was administered, with a preference for administration in the same arm used for the first dose. Follow up visits are scheduled to occur 1, 2, and 4 weeks after each vaccination (Days 8, 15, 29, 36, 43, and 57), as well as 3 months, 6 months and 12 months after 2<sup>nd</sup> vaccination (Days 119, 209, and 394). Safety endpoints will be assessed at these visits as well as blood drawn for immunogenicity assays. Additional safety and reactogenicity data will be solicited via phone calls to subjects 1 and 2 days post each vaccination (Days 2, 3, 30, and 31).

To determine early safety signals for this Phase 1 study, vaccination proceeded in a staged fashion. Sentinel subject dosing began with four subjects in cohort 1 (25 mcg). The four sentinel subjects for cohort 2 (100 mcg) were enrolled no earlier than one day after enrollment of the last of the four sentinel subjects in cohort 1. When no halting rules were met for these eight sentinel subjects after Day 5, then full enrollment proceeded first with the remaining subjects in cohort 1, followed by the remaining subjects in cohort 2, without interruption. When no halting rules were met after all subjects in cohort 2 completed Day 8, dosing of four sentinel subjects began in cohort 3. When no halting rules were met after Day 5, then full enrollment of cohort 3 proceeded.

When no halting rules were met after all subjects in cohorts 1 and 2 completed Day 8, dosing began for cohorts 4 (25 mcg; 56-70 years of age) and 5 (100 mcg; 56-70 years of age). When no halting rules were met after all subjects in cohorts 4 and 5 had completed Day 8, dosing began for cohorts 7 (25 mcg;  $\geq 71$  years of age) and 8 (100 mcg;  $\geq 71$  years of age). Subjects were enrolled simultaneously in cohorts 10-12; there was no staging.

### **Vaccination Arms**

| <b>Cohort</b> | <b>Sample Size</b> | <b>Age</b> | <b>First and Second Dose</b> |
|---------------|--------------------|------------|------------------------------|
| 1             | 15                 | 18-55      | 25 µg mRNA-1273              |
| 2             | 15                 | 18-55      | 100 µg mRNA-1273             |
| 3             | 15                 | 18-55      | 250 µg mRNA-1273             |
| 4             | 10                 | 56-70      | 25 µg mRNA-1273              |
| 5             | 10                 | 56-70      | 100 µg mRNA-1273             |
| 7             | 10                 | $\geq 71$  | 25 µg mRNA-1273              |
| 8             | 10                 | $\geq 71$  | 100 µg mRNA-1273             |
| 10            | 15                 | 18-55      | 50 µg mRNA-1273              |
| 11            | 10                 | 56-70      | 50 µg mRNA-1273              |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

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| 12 | 10 | $\geq 71$ | 50 µg mRNA-1273 |
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*Note:* Cohorts 6, 9, and 13 were not enrolled as decided by the study team and therefore are not included.

On vaccination days, all females of childbearing potential had a urine pregnancy test done. All subjects had vital signs measured and a physical examination pre-vaccination. Blood was collected pre-vaccination for immunogenicity testing. On vaccination days, clinical safety laboratory tests were collected pre-vaccination. Vaccine was then administered by intramuscular injection.

Subjects were observed for at least 60 minutes after the injection was given. Reactogenicity was measured by the occurrence of solicited injection site and systemic AEs. Subjects maintained a memory aid through 7 days post each vaccination recording temperature, solicited local and systemic symptoms. Unsolicited non-serious AEs were collected from the time of first study vaccination through approximately 28 days after the last vaccination. From Day 57 through completion of study participation, only SAEs, MAAEs, and NOCMCs will be recorded as AEs in the study database. Clinical safety labs will be collected on Days 1, 8, 29 and 36.

Evaluation of immunogenicity will include quantitation of antibodies to the SARS-CoV-2 S protein at multiple timepoints following each study vaccination as measured by ELISA, pseudovirus and live virus neutralization assays, PRNT, FRNT and nLuc. In addition, exploratory studies to characterize cell mediated immune responses are planned. Venous blood will also be collected at multiple time points following study vaccination for the secondary research use of serum, plasma and peripheral blood mononuclear cells (PBMCs).

#### 4. METHODS FOR SAFETY ASSESSMENTS

A summary of the procedures for vaccination and follow-up of the study cohort is provided in the protocol.

Brief descriptions of the collection and protocol definitions of adverse events, serious adverse events, and the grading scales for solicited events, clinical laboratory results, and vital signs are excerpted from the protocol (Version 4.0, 20 May 2020) and included in [Appendix A](#).

#### 5. REVIEW OF THE SAFETY DATA

##### 5.1 Overview

The safety data presented in this report focus on both solicited and unsolicited events experienced following product administration. Adverse events are reported to the staff at Kaiser Permanente Washington Health Research Institute, Emory Children's Center, Hope Clinic of the Emory Vaccine Center, and Vaccine Research Center.



The report includes the available safety data from subjects who received study product with data entered into the study database as of the data cutoff date of October 7, 2020. The monitoring of the data collected to date remains ongoing. The data are not considered clean.

## 5.2 Study Status

Enrollment was initiated on 16 March 2020. As of the data cutoff date for this report, 120 subjects have been enrolled, 120 subjects had received the first dose of vaccine and 116 subjects had received 2 doses of vaccine. Two hundred fifty six potential subjects were screened to accrue this number, for an overall screening failure rate of 53%. Thirty six subjects were found to be eligible but were not enrolled; these are considered screen failures for the purposes of this report. The most common reasons for screening failure were screening laboratory evaluations are not within acceptable normal ranges (41%), Systolic BP is not within the allowable range of 85 to 150 mmHg, inclusive (8%), and has any medical disease or condition that precludes study participation (4%).

**Tables 2A-2F** present demographic characteristics (sex, ethnicity, race, and age) of the subjects enrolled in the study who have received study product.

Of the 60 subjects enrolled into the 18-55 years of age cohorts, 52 (87%) reported their ethnicity as not Hispanic or Latino; 53 (88%) subjects reported their race as White, 3 (5%) subjects reported their race as Asian, 2 (3%) subjects reported their race as Black, 1 (2%) subject reported their race as American Indian or Alaska Native, and 1 (2%) subject reported their race as Unknown. The mean age in the 18-55 years of age cohorts is 34.0 years and the range is 18 to 54 years; the mean BMI is 24.79 kg/m<sup>2</sup> and the range is 18.5 to 32.6 kg/m<sup>2</sup>.

Of the 30 subjects enrolled into the 56-70 years of age cohorts, 30 (100%) reported their ethnicity as not Hispanic or Latino; 27 (90%) subjects reported their race as White, 1 (3%) subject reported their race as Asian, 1 (3%) subject reported their race as Black, and 1 (3%) subject reported their race as Multi Racial. The mean age in the 56-70 years of age cohorts is 63.9 years and the range is 56 to 70 years; the mean BMI is 24.17 kg/m<sup>2</sup> and the range is 20.8 to 29.5 kg/m<sup>2</sup>.

Of the 30 subjects enrolled into the ≥71 years of age cohorts, 28 (93%) reported their ethnicity as not Hispanic or Latino; 29 (97%) subjects reported their race as White, and 1 (3%) subject reported their race as Asian. The mean age in the ≥71 years of age cohorts is 73.5 years and the range is 71 to 83 years; the mean BMI is 25.15 kg/m<sup>2</sup> and the range is 19.9 to 29.7 kg/m<sup>2</sup>.

**Table 2G** shows the percentage of subjects in each vaccination group that have completed the study milestones and **Tables 2H-2J** display subject disposition. A total of 256 subjects were screened, and 120 were enrolled and 120 received treatment. 120/120 (100%) subjects have completed the Day 57 visit and 116/120 (97%) have completed the Day 119 visit. As of the data cutoff, four subjects discontinued treatment on the study; three of those subjects discontinued due

to an AE (Hives on Lower Extremities, Sore Throat, and Maculopapular Rash), the other subject discontinued treatment due to potential COVID-19 exposure.

For a listing of subjects who have discontinued treatment and subjects who have terminated early from the study, see [Table 2K](#).

### 5.3 Halting Rules Surveillance

The status of the study Halting Rules is summarized in [Table 1](#).

**TABLE 1: Study Halting Rules**

| Halting Rule # | Halting Rule Description   | Number of Subjects n (%) |
|----------------|--|--------------------------|
| 1              | Any subject experiences an SAE after administration of the vaccine that is considered related to vaccine.  | 0 (0)                    |
| 2              | Any subject experiences laryngospasm, bronchospasm or anaphylaxis within 24 hours after administration of vaccine that is considered related to vaccine.   | 0 (0)                    |
| 3              | Any subject experiences ulceration, abscess or necrosis at the injection site that is considered related to vaccine administration.  | 0 (0)                    |
| 4              | Two (2) or more subjects experience an allergic reaction such as generalized urticaria (defined as occurring at three or more body parts) within 72 hours after administration of vaccine that is considered related to vaccine.   | 0 (0)                    |
| 5              | Three (3) or more subjects experience a Grade 3 AE (systemic and/or clinical laboratory abnormality), in the same Preferred Terms based on the Medical Dictionary for Regulatory Activities (MedDRA) coding, that lasted at least 48 hours after administration of the vaccine and is considered related to the vaccine. Clinical laboratory abnormalities are not subject to the time window. | 1 (0.8%)                 |
| 6              | Additionally, any AE for which the investigator checks the box for "In the opinion of the site investigator, this event should be evaluated for possible contribution toward the halting criteria for the group, cohort, or study" will trigger an automatic email from the EDC, even if it does not meet any of the requirements in the table above.  | 1 (0.8%)                 |

**NOTE:** No halting criteria have been met as of October 7, 2020.

One subject had a severe lipase value reported, which was determined to be related to study treatment, therefore meeting 1 of the 3 needed to halt the study per Halting Rule #1 in [Table 1](#) above.

One subject reported moderate abdominal discomfort which was initially determined to be related to the study treatment and which, in the opinion of the site investigator, was to be evaluated for possible contribution toward the halting criteria. Upon further discussions with the subject and the subject's primary care physician, it was determined that this was not related to the study treatment, but was a medically attended adverse event (MAAE) consistent with acute pancreatitis, related to

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

dietary intake. Therefore, this did not meet study halting criteria. These updates will be made in the study database and will be reflected in subsequent safety reports.

Details of reported serious adverse events, if any, are included in [Table 3A](#).

## 5.4 Adverse Events

Details of reported serious adverse events, medically attended adverse events (MAAEs), and new onset chronic medical conditions, if any, are included in [Table 3A and 3B](#). Thirty three MAAEs have been reported in 24 subjects as of data cutoff. One subject (6%) in the 18-55 years of age cohort that received the 250 mcg dose reported 4 MAAEs after receiving one dose of the investigational product, with one in the Respiratory, thoracic and mediastinal disorders SOC, one in the Gastrointestinal disorders SOC, one in the Infections and infestations SOC, and one in the Reproductive system and breast disorders SOC. One subject (6%) in the 56-70 years of age cohort that received the 100 mcg dose reported 3 MAAEs after receiving one dose of the investigational product, with one in the Infections and infestations MedDRA® System Organ Class (SOC), and two in the Skin and subcutaneous tissue disorders SOC. Four other subjects each experienced 2 separate MAAEs. One subject in the 18-55 years of age cohort that received the 250 mcg dose reported 1 MAAE in the Gastrointestinal disorders SOC that was initially determined to be related to study product; this was the same subject noted in Section 5.3 above that experienced abdominal discomfort. As noted above, after further discussion, this was determined to not be related to study treatment and will be reflected in subsequent reports. Therefore, all 33 (100%) MAAEs were assessed to be not related to the study product.

[Tables 4A-4I](#) summarize all unsolicited adverse events reported for subjects as of the data cutoff date. [Tables 4A, 4B, and 4C](#) classify each event in terms of MedDRA® System Organ Class (SOC), severity, and relationship to vaccination. [Tables 4D-4I](#) classify the events by MedDRA® SOC, Preferred Term (PT), relationship to vaccination, and severity. [Figure 1A-C](#) is a graphical representation of the number and severity of all unsolicited adverse events by System Organ Class. [Appendix B](#) is a listing of all unsolicited events grouped by cohort and dose number.

At the time of data cutoff, in the 18-55 years of age cohorts, 44 subjects (73%) had reported 123 unsolicited adverse events. Ninety four (76%) of the events were determined to be mild (Grade 1) severity, twenty seven (22%), were determined to be moderate (Grade 2) severity, and two (2%) were determined to be severe (Grade 3) severity; 41 (33%) of the events were determined to be related to study product, and 82 (67%) were determined to be not related to study product. One incidence of mild lymphadenopathy was reported in the Blood and lymphatic system disorders SOC. Five events were reported within the Cardiac Disorders SOC, with all reported as mild Bradycardia. One mild incidence of vertigo was reported in the Ear and labyrinth disorders SOC. Two events were reported within the Eye Disorder SOC, including one incidence of mild eye irritation and one incidence of mild Scintillating scotoma. Seventeen events were reported within

the Gastrointestinal SOC, including 2 incidences of abdominal discomfort (1 mild and 1 moderate), 2 incidences of moderate abdominal pain, 1 incidence of mild abdominal pain upper, 1 incidence of mild anal fissure, 1 incidence of moderate diarrhoea, 2 incidences of mild dyspepsia, 1 incidence of mild faeces discoloured, 1 incidence of mild flatulence, 1 incidence of mild lip disorder, 1 incidence of moderate tooth impacted, and 4 incidences of vomiting (2 mild and 2 moderate). Twenty one events were reported within the General Disorders and Administration site SOC, including 1 incidence of mild fatigue, 1 incidence of moderate feeling jittery, 3 incidences of mild injection site bruising, 2 incidences of injection site erythema (1 mild and 1 moderate), 1 incidence of mild injection site irritation, 4 incidences of mild injection site pruritus, 1 incidence of moderate Malaise, 1 incidence of mild vaccination site movement impairment, 6 incidences of mild vessel puncture site bruise, and 1 incidence of mild vessel puncture site haemorrhage. One event was reported in the Immune system disorders SOC (mild seasonal allergy). Seven events were reported within the Infections and infestations SOC, including 1 incidence of moderate epididymitis, 1 incidence of moderate gastroenteritis, 1 incidence of moderate hordeolum, 1 incidence of moderate infected cyst, 1 incidence of mild pustule, 1 incidence of mild upper respiratory tract infection, and one incidence of mild urinary tract infection. Thirteen events were reported within the Injury, Poisoning and Procedural Complications SOC, including 3 incidences of mild contusion, 4 incidences of muscle strain (3 mild and 1 moderate), 3 incidences of mild skin abrasion, 1 incidence of mild skin laceration, 1 incidence of mild thermal burn, and 1 incidence of mild wound. Two events were reported within the Investigations SOC, including 1 incidence of mild blood glucose decreased, and 1 incidence of mild heart rate increased. Six events were reported in the Metabolism and nutrition disorders, including 5 incidences of decreased appetite (3 mild and 2 moderate), and 1 moderate hypoglycaemia. Nine events were reported in the Musculoskeletal and connective tissue disorders, including 1 incidence of mild arthralgia, 2 incidences of muscle spasm (1 mild and 1 moderate), 1 incidence of moderate muscle strain, 1 incidence of mild muscular weakness, 1 incidence of mild myalgia, 1 incidence of mild neck pain, 1 incidence of mild pain in extremity, and 1 incidence of mild pain in jaw. Eight events were reported within the Nervous System Disorders SOC, including 2 incidences of dizziness (1 mild and 1 severe), 4 incidences of headache (1 mild and 3 moderate), 1 incidence of mild presyncope and 1 incidence of severe syncope. Three events were reported in the Psychiatric disorders SOC, including 1 incidence of mild anxiety, 1 incidence of moderate attention deficit hyperactivity disorder, and 1 incidence of mild insomnia. Four events were reported in the Reproductive system and breast disorder SOC, including 1 incidence of mild breast pain, 1 incidence of mild vaginal haemorrhage and 2 incidences of mild vulvovaginal pruritis. Twelve events were reported within the Respiratory, Thoracic and Mediastinal Disorder SOC, including 1 incidence of mild diaphragmatic spasm, 1 incidence of mild dyspnea exertional, 3 incidences of nasal congestion (2 mild and 1 moderate), 5 incidences of mild oropharyngeal pain, and 2 incidences of mild upper airway cough syndrome. Seven events were reported within the Skin and Subcutaneous tissue disorder SOC, including 1 incidence of mild dermatitis contact, 1 incidence of mild erythema, 1 incidence of moderate hyperhidrosis, 1 incidence of moderate night sweats, 1 incidence of mild petechiae, 1 incidence of

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

mild rash, and 1 incidence of mild urticaria. Four events were reported within the Vascular Disorders SOC, including 1 incidence of mild hypertension, 1 incidence of mild hypotension, 1 incidence of mild systolic hypertension and 1 incidence of mild vasodilation.

At the time of data cutoff, in the 56-70 years of age cohorts, 22 subjects (73%) had reported 32 unsolicited adverse events. Seventeen (53%) of the events were determined to be mild (Grade 1) severity, thirteen (41%), were determined to be moderate (Grade 2) severity, and two (6%) were determined to be severe (Grade 3) severity; 4 (13%) of the events were determined to be related to study product, and 28 (88%) were determined to be not related to study product. Two events were reported within the Cardiac disorder SOC, two incidences of mild bradycardia. One event was reported within the Ear and labyrinth disorder SOC, one incidence of mild vertigo; two events were reported in the Gastrointestinal disorders SOC, including 1 incidences of moderate abdominal discomfort and 1 incidence of mild haemorrhoids; two events were reported within the General Disorders and Administration site SOC, 2 incidences of mild injection site bruising. Four events were reported within the Infections and infestations SOC, including 1 incidence of moderate onychomycosis, 1 incidence of moderate paronychia, 1 incidence of moderate urinary tract infection, and 1 incidence of severe viral infection. Six events were reported within the Injury, poisoning and procedural Complications SOC, including 1 incidence of mild arthropod sting, 1 incidence of moderate exposure via inhalation, 1 incidence of moderate limb injury, one incidence of mild muscle strain, 1 incidence of mild skin laceration, and 1 incidence of moderate tooth fracture. One incidence of moderate bone density decreased was reported within the Investigations SOC. Two events were reported in the Metabolism and nutrition disorders, including 1 incidence of moderate decreased appetite, and 1 severe hypoglycaemia. One event was reported in the Musculoskeletal and connective tissue disorders SOC, which was 1 mild incidence of pain in extremity. Four events were reported within the Nervous System Disorders SOC, including 1 incidence of mild dizziness, 1 incidence of mild headache and 2 incidences of sciatica (1 mild and 1 moderate). One event was reported in the Psychiatric disorders SOC, including 1 incidence of mild insomnia. Three events were reported within the Respiratory, thoracic and mediastinal Disorder SOC, including 1 incidence of moderate nasal congestion and 2 incidences of mild oropharyngeal pain. Two events were reported within the Skin and Subcutaneous tissue disorder SOC, including 1 incidence of moderate dermatitis contact and 1 incidence of moderate rash maculo-papular. One event was reported within the Vascular Disorders SOC, 1 incidence of mild systolic hypertension.

At the time of data cutoff, in the 71 years of age and over cohorts, 23 subjects (77%) had reported 59 unsolicited adverse events. Fifty seven (97%) of the events were determined to be mild (Grade 1) severity and two (3%) were determined to be moderate (Grade 2) severity; 14 (24%) of the events were determined to be related to study product, and 45 (76%) were determined to be not related to study product. Two events were reported within the Cardiac disorder SOC, two incidences of mild bradycardia. Twelve events were reported within the General Disorders and Administration site SOC, including 2 incidences of mild increased energy, 1 incidence of mild

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

fatigue, 3 incidences of mild injection site bruising, 1 incidence of mild injection site erythema, 1 incidence of mild injection site pruritis, and 4 incidences of mild vessel puncture site bruise. Two events were reported in the Infections and infestations SOC; 1 incidence of mild pustule and 1 incidence of mild urinary tract infection. Eighteen events were reported within the Injury, poisoning and procedural Complications SOC, including 2 incidences of mild arthropod bite, 3 incidences of mild contusion, 2 incidences of mild injury, 1 incidence of mild limb injury, 1 incidence of mild procedural pain, 6 incidences of mild skin abrasion, 1 incidence of mild sunburn, 1 incidence of mild thermal burn, and 1 incidence of mild tooth fracture. Five events were reported in the Musculoskeletal and connective tissue disorders, including 1 incidence of moderate arthritis, 1 incidence of mild joint swelling, 1 incidence of mild muscle tightness, 1 incidence of moderate musculoskeletal chest pain, and 1 incidence of mild myalgia. One event was reported in the Neoplasms benign, malignant and unspecified (incl cysts and polyps) SOC, which was 1 incidence of mild squamous cell carcinoma. Four events were reported within the Nervous System Disorders SOC, including 3 incidences of mild dizziness and 1 incidence of mild visual field defect. Three events were reported in the Psychiatric disorders SOC, including 1 incidence of mild anxiety and 2 incidences of mild sleep disorder. One event was reported in the Respiratory, thoracic, and mediastinal disorders SOC, including 1 incidence of mild oropharyngeal pain. Eight events were reported within the Skin and Subcutaneous tissue disorder SOC, including 1 incidence of mild blister, 1 incidence of mild dermatitis, 1 incidence of mild dermatitis contact, 2 incidences of mild night sweat, 1 incidence of mild pruritus, 1 incidence of mild rash, and 1 incidence of mild skin irritation. Three events were reported in the Vascular disorders SOC, including 2 incidences of mild hypertension, and 1 incidence of mild systolic hypertension.

Refer to [Appendix B](#) for a detailed listing of moderate and severe non-serious, unsolicited, adverse events.

## 5.5 Solicited Events and Symptoms

Solicited events data, collected in-clinic pre-vaccination, post-vaccination and via memory aid through 7 days after vaccination, are summarized by symptom in [Figure 2A\(i, ii\)](#)-[2C\(i, ii\)](#) and [Table 5A\(i, ii, iii\)](#)-[5C\(i, ii, iii\)](#), which report the maximum severity experienced by each subject over the 7-day post-vaccination reporting period, separated by Dose 1 and Dose 2.

[Figures 3A\(i, ii, iii\)](#) and [4A\(i, ii, iii\)](#) summarize the solicited event data across all vaccination groups and display the maximum severity experienced by each subject post-vaccination and on each day for all systemic and all local symptoms, respectively.

The graphical summaries of solicited events included in this report convey the number of subjects who experienced a maximum severity of mild ([yellow](#)), moderate ([orange](#)), or severe ([red](#)) during the post-vaccination period.

**Figures 5A(i, ii, iii)-5L(i, ii, iii)** display subjects who experienced a mild, moderate, or severe event for each symptom for each day post-vaccination, separated by Dose 1 and Dose 2.

Thirty-five (58.3%) subjects in the 18-55 age group reported experiencing a maximum mild/grade 1 solicited local event for at least one day, 18 (30%) subjects experienced a maximum moderate/grade 2 solicited local event for at least one day, and 2 (3.3%) subjects experienced a maximum severe/grade 3 event for at least one day. Post any vaccination, 11 (18.3%) subjects reported experiencing a maximum of mild erythema/redness. Nine (15%) subjects reported experiencing a maximum of mild induration/swelling with 1 (1.7%) subject experiencing a maximum of moderate induration/swelling. Thirty-eight (63.3%) subjects reported experiencing a maximum of mild injection site pain with 17 (28.3%) experiencing a maximum of moderate injection site pain.

Fifteen (25%) subjects in the 18-55 age group reported experiencing a maximum mild/grade 1 solicited systemic event for at least one day, 32 (53.3%) subjects experienced a maximum moderate/grade 2 solicited systemic event for at least one day, and 4 (6.7%) subjects experienced a maximum severe/grade 3 event for at least one day. Post any vaccination, 7 (11.7%) subjects reported experiencing a maximum of mild arthralgia, and 8 (13.3%) subjects reporting a maximum of moderate arthralgia. 15 (25%) subjects reported experiencing a maximum of mild fatigue, 22 (36.7%) subjects reported experiencing a maximum of moderate fatigue, and 2 (3.3%) subjects experiencing a maximum of severe fatigue. Eleven (18.3%) subjects reported experiencing a maximum of mild fever, 3 (5%) subjects reported experiencing a maximum of moderate fever, and 1 (1.7%), subject experienced a maximum of severe fever. Fifteen (25%) subjects reported experiencing a maximum of mild feverishness, 10 (16.7%) subjects reported experiencing a maximum of moderate feverishness, and 3 (5%), subjects experienced a maximum of severe feverishness. Twenty-four (40%) subjects reported experiencing a maximum of mild headache, 13 (21.7%) subjects reported experiencing a maximum of moderate headache, and 2 (3.3%) subjects experienced a maximum of severe headache. Twelve (20%) subjects reported experiencing a maximum of mild myalgia, 18 (30%) subjects reported experiencing a maximum of moderate myalgia, and 1 (1.7%) subject experienced a maximum of severe myalgia. Nine (15%) subjects reported experiencing a maximum of mild nausea, 5 (8.3%) subjects reported experiencing a maximum of moderate nausea, and 1 (1.7%) subject experienced a maximum of severe nausea.

Nineteen (63.3%) subjects in the 56-70 age group reported experiencing a maximum mild/grade 1 solicited local event for at least one day, 6 (20%) subjects experienced a maximum moderate/grade 2 solicited local event for at least one day, and 1 (3.3%) subject experienced a maximum severe/grade 3 solicited local event for at least one day. Post any vaccination, 4 (13.3%) subjects reported experiencing a maximum of mild erythema/redness, and 1 (3.3%) subject reported experiencing a maximum of severe erythema/redness. Seven (23.3%) subjects reported experiencing a maximum of mild induration/swelling, and 4 (13.3%) subjects reported experiencing a maximum of moderate induration/swelling. Twenty-one (70%) subjects reported

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



experiencing a maximum of mild injection site pain, and 3 (10%) subjects experienced a maximum of moderate injection site pain.

Eleven (36.7%) subjects in the 56-70 age group reported experiencing a maximum mild/grade 1 solicited systemic event for at least one day, 10 (33.3%) subjects experienced a maximum moderate/grade 2 solicited systemic event for at least one day, and 1 (3.3%) subject experienced a maximum severe/grade 3 event for at least one day. Post any vaccination, 3 (10%) subjects reported experiencing a maximum of mild arthralgia, and 4 (13.3%) subjects reported a maximum of moderate arthralgia. Eight (26.7%) subjects reported experiencing a maximum of mild fatigue, and 8 (26.7%) subjects reported experiencing a maximum of moderate fatigue. Two (6.7%) subjects reported experiencing a maximum of mild fever and 1 (3.4%) subject reported experiencing a maximum of severe fever. Five (16.7%) subjects reported experiencing a maximum of mild feverishness, and 4 (13.3%) subjects reported experiencing a maximum of moderate feverishness. Twelve (40%) subjects reported experiencing a maximum of mild headache, and 2 (6.7%) subjects reported experiencing a maximum of moderate headache. Eleven (36.7%) subjects reported experiencing a maximum of mild myalgia, and 5 (16.7%) subjects reported experiencing a maximum of moderate myalgia. Five (16.7%) subjects reported experiencing a maximum of mild nausea, and 3 (10%) subjects reported experiencing a maximum of moderate nausea.

Nineteen (63.3%) subjects in the 71+ age group reported experiencing a maximum mild/grade 1 solicited local event for at least one day, 6 (20%) subjects reported experiencing a maximum moderate/grade 2 solicited local event for at least one day. Post any dose, 8 (26.75%) subjects reported experiencing a maximum of mild erythema/redness. Seven (23.3%) subjects reported experiencing a maximum of mild induration/swelling. Twenty-four (80%) subjects reported experiencing a maximum of mild injection site pain, and 1 (3.3%) subject reported experiencing a maximum of moderate injection site pain.

Twelve (40%) subjects in the 71+ age group reported experiencing a maximum mild/grade 1 solicited systemic event for at least one day, 5 (16.7%) subjects reported experiencing a maximum moderate/grade 2 solicited systemic event for at least one day, and 1 (3.3%) subject reported experiencing a maximum severe/grade 3 solicited systemic event for at least one day. Post dose 1, 4 (13.3%) subjects reported experiencing a maximum of mild arthralgia. Nine (30%) subjects reported experiencing a maximum of mild fatigue, 5 (16.7%) subjects reported experiencing a maximum of moderate fatigue, and 1 (3.3%) subject reported experiencing a maximum of severe fatigue. One (3.3%) subject reported experiencing a maximum of mild fever. Four (13.3%) subjects reported experiencing a maximum of mild feverishness, and 1 (3.3%) subject reported experiencing a maximum of moderate feverishness. Eight (26.7%) subjects reported experiencing a maximum of mild headache, and 1 (3.3%) subject reported experiencing a maximum of moderate headache. Ten (33.3%) subjects reported experiencing a maximum of mild myalgia, and 1 (3.3%) subject reported experiencing a maximum of moderate myalgia. One (3.3%) subject reported experiencing a maximum of mild nausea.



A listing of systemic and local solicited events is provided in [Appendix C1-C2](#). The listing is limited to subjects who experienced a symptom of moderate or greater severity on at least one occasion.

[Appendix D](#) is a listing of all severe systemic solicited events contributing to halting criteria along with their attributions.

## 5.6 Clinical Laboratory Results and Vital Signs

[Tables 6A-6K](#) summarize the results of the scheduled hematology and chemistry clinical laboratory parameters conducted at the protocol specified visits. [Figure 6A-C](#) displays abnormal results by laboratory parameter and severity and takes into account all values reported after vaccination (scheduled and supplemental).

[Appendix E](#) includes listings of clinical laboratory results for subjects who experience abnormal hematology and chemistry results at any time post-vaccination.

Forty-nine (82%) subjects in the 18-55 age group experienced a maximum mild/grade 1 abnormal hematology result post-vaccination, and 6 (10%) subjects experienced a maximum moderate/grade 2 abnormal hematology result post-vaccination. Forty-eight (80%) subjects experienced a maximum mild abnormal hemoglobin result and 6 (10%) of subjects experienced a maximum moderate abnormal hemoglobin result. Seven (12%) subjects experienced mild leukopenia.

Twenty-six (87%) subjects in the 56-70 age group experienced a maximum mild/grade 1 abnormal hematology result post-vaccination, 2 (7%) subjects experienced a maximum moderate/grade 2 abnormal hematology result post-vaccination, and 2 (7%) subjects experienced a maximum severe/grade 3 abnormal hematology result post-vaccination. Twenty-six (87%) subjects in the 56-70 age group experienced a maximum mild abnormal hemoglobin result, 2 (7%) subjects experienced a maximum moderate abnormal hemoglobin result, and 2 (7%) subjects experienced a maximum severe abnormal hemoglobin result.

Twenty-eight (93%) subjects in the 71+ age group experienced a maximum mild/grade 1 abnormal hematology result post-vaccination. Twenty-seven (90%) subjects experienced a maximum mild abnormal hemoglobin result, 4 (13%) subjects experienced a maximum mild leukopenia result, and 2 (7%) subjects experienced a maximum mild abnormal platelet result.

Seven (23%) subjects in the 18-55 age group experienced a maximum mild/grade 1 abnormal chemistry result post-vaccination, 1 (3%) subject experienced a maximum moderate/grade 2 abnormal chemistry result post-vaccination, and 1 (3%) subject experienced a maximum severe/grade 3 abnormal chemistry result post-vaccination. Three (10%) subjects experienced a maximum mild abnormal alanine aminotransferase result, 1 (3%) subject experienced a maximum mild abnormal aspartate aminotransferase result, 2 (7%) subjects experienced a maximum mild

abnormal bilirubin result and 1 (3%) subject experienced a maximum moderate bilirubin result. One (2%) subject experienced a maximum mild and 1 (3%) subject experienced a maximum severe abnormal serum lipase result.

Two (7%) subjects in the 56-70 age group experienced a maximum mild/grade 1 abnormal chemistry result post-vaccination. One (3%) subject experienced a maximum mild abnormal aspartate aminotransferase result, and 1 (3%) subject experienced a maximum mild abnormal serum lipase result.

Three (10%) subjects in the 71+ age group experienced an abnormal chemistry result post-vaccination. Two (7%) subjects experienced a maximum mild/grade 1 abnormal serum lipase result and 1 (3%) subject experienced a maximum severe/grade 3 abnormal serum lipase result.

**Appendix F** includes a listing of vital signs for subjects who experience abnormal vital signs at any time post-vaccination.

## **5.7 Protocol Adherence**

**Tables 7A-7C** summarizes the protocol deviations for this study by category and type. A full listing of protocol deviations is provided in **Appendix G**.

Among the subjects in the 18-55 years of age cohorts, a total of 32 deviations were reported in 21 subjects. There were 14 deviations reported for too few aliquots obtained, 8 for required procedure done incorrectly, 4 for a visit conducted out of window, 2 for required procedure not conducted, and one deviation each was reported for breach of confidentiality, non-required lab tests performed, safety labs collected out of window, and required procedure done incorrectly.

Among the subjects in the 56-70 years of age cohorts, a total of 4 deviations were reported in 4 subjects. There were 2 deviations reports for too few aliquots obtained, and one deviation each was reported for missed visit/visit not conducted and visit conducted out of window.

Among the subjects in the  $\geq 71$  years of age cohorts, a total of 4 deviations were reported in 4 subjects. There were 3 deviations reported for too few aliquots obtained and one deviation for specimen result not obtained.

There were two non-subject specific protocol deviation reported. One involved a freezer storing the investigational product (IP) was out of range on April 17, 2020. The IP was immediately moved to a different freezer at the site. The study team was alerted of this and the site was instructed to continue use of the IP. The second involved inadvertent disclosure of study participation by one subject to other study subjects via email and was reported by the study site as an unanticipated problem (UP). A total of 3 participants who screened but were not enrolled, and 1 subject who was screened and enrolled, exposed their names and email addresses by using “reply all” to an email

string in which they were blind carbon copied (BCC). Due to an IT glitch at the clinical site, when a study participant, who screened but did not enroll in the study, used "reply all" in an email and included their name and information about their screening status, the email was seen by 9 other study participants, instead of just the sender of the original email. No other information including medical history was disclosed. Two other subjects who screened for the study and 1 who screened and enrolled in the study also replied to the email thread indicating they believed they were included in error. Their names were also disclosed as having screened for the study, however, no other information including medical history was disclosed. All subjects whose names were disclosed and who opened the email were notified of the event and that the event was being reported as a UP.

### **5.8 Pregnancies**

A listing of pregnancies is provided in [Appendix H](#). No pregnancies have been reported as of data cutoff.

## **6. TABLES AND FIGURES**

**TABLE 2A:**  
**Summary of Categorical Demographic and Baseline Characteristics**  
**by Vaccination Group - All Subjects 18-55 Years of Age**

|                      |  | 25 µg<br>mRNA-1273<br>(N=15) |     | 50 µg<br>mRNA -1273<br>(N=15) |    | 100 µg<br>mRNA -1273<br>(N=15) |    | 250 µg<br>mRNA -1273<br>(N=15) |    | All Subjects<br>(N=60) |    |
|----------------------|--|------------------------------|-----|-------------------------------|----|--------------------------------|----|--------------------------------|----|------------------------|----|
| Demographic Category | Characteristic                               | n                            | %   | n                             | %  | n                              | %  | n                              | %  | n                      | %  |
| Sex                  | Male   | 9                            | 60  | 9                             | 60 | 7                              | 47 | 6                              | 40 | 31                     | 52 |
|                      | Female                                       | 6                            | 40  | 6                             | 40 | 8                              | 53 | 9                              | 60 | 29                     | 48 |
| Ethnicity            | Not Hispanic or Latino                       | 14                           | 93  | 14                            | 93 | 12                             | 80 | 12                             | 80 | 52                     | 87 |
|                      | Hispanic or Latino                           | 1                            | 7   | 1                             | 7  | 3                              | 20 | 2                              | 13 | 7                      | 12 |
|                      | Not Reported                                 | .                            | .   | .                             | .  | .                              | .  | 1                              | 7  | 1                      | 2  |
|                      | Unknown                                      | .                            | .   | .                             | .  | .                              | .  | .                              | .  | .                      | .  |
| Race                 | American Indian or<br>Alaska Native          | .                            | .   | .                             | .  | 1                              | 7  | .                              | .  | 1                      | 2  |
|                      | Asian  | .                            | .   | 2                             | 13 | .                              | .  | 1                              | 7  | 3                      | 5  |
|                      | Native Hawaiian or<br>other Pacific Islander | .                            | .   | .                             | .  | .                              | .  | .                              | .  | .                      | .  |
|                      | Black  | .                            | .   | .                             | .  | 2                              | 13 | .                              | .  | 2                      | 3  |
|                      | White  | 15                           | 100 | 13                            | 87 | 11                             | 73 | 14                             | 93 | 53                     | 88 |
|                      | Multi Racial                                 | .                            | .   | .                             | .  | .                              | .  | .                              | .  | .                      | .  |
|                      | Unknown                                      | .                            | .   | .                             | .  | 1                              | 7  | .                              | .  | 1                      | 2  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 2B:**  
**Summary of Categorical Demographic and Baseline Characteristics**  
**by Vaccination Group - All Subjects 56-70 Years of Age**

|                      |   | 25 µg<br>mRNA-1273<br>(N=10) |     | 50 µg<br>mRNA-1273<br>(N=10) |     | 100 µg<br>mRNA-1273<br>(N=10) |     | All Subjects<br>(N=30) |     |
|----------------------|---|------------------------------|-----|------------------------------|-----|-------------------------------|-----|------------------------|-----|
| Demographic Category | Characteristic                            | n                            | %   | n                            | %   | n                             | %   | n                      | %   |
| Sex                  | Male                                      | 3                            | 30  | 5                            | 50  | 5                             | 50  | 13                     | 43  |
|                      | Female                                    | 7                            | 70  | 5                            | 50  | 5                             | 50  | 17                     | 57  |
| Ethnicity            | Not Hispanic or Latino                    | 10                           | 100 | 10                           | 100 | 10                            | 100 | 30                     | 100 |
|                      | Hispanic or Latino                        | .                            | .   | .                            | .   | .                             | .   | .                      | .   |
|                      | Not Reported                              | .                            | .   | .                            | .   | .                             | .   | .                      | .   |
|                      | Unknown                                   | .                            | .   | .                            | .   | .                             | .   | .                      | .   |
| Race                 | American Indian or Alaska Native          | .                            | .   | .                            | .   | .                             | .   | .                      | .   |
|                      | Asian                                     | .                            | .   | 1                            | 10  | .                             | .   | 1                      | 3   |
|                      | Native Hawaiian or other Pacific Islander | .                            | .   | .                            | .   | .                             | .   | .                      | .   |
|                      | Black                                     | .                            | .   | 1                            | 10  | .                             | .   | 1                      | 3   |
|                      | White                                     | 10                           | 100 | 7                            | 70  | 10                            | 100 | 27                     | 90  |
|                      | Multi Racial                              | .                            | .   | 1                            | 10  | .                             | .   | 1                      | 3   |
|                      | Unknown                                   | .                            | .   | .                            | .   | .                             | .   | .                      | .   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 2C:**  
**Summary of Categorical Demographic and Baseline Characteristics**  
**by Vaccination Group - All Subjects ≥71 Years of Age**

|                      |  | 25 µg<br>mRNA-1273<br>(N=10) |    | 50 µg<br>mRNA-1273<br>(N=10) |     | 100 µg<br>mRNA-1273<br>(N=10) |     | All Subjects<br>(N=30) |    |
|----------------------|--|------------------------------|----|------------------------------|-----|-------------------------------|-----|------------------------|----|
| Demographic Category | Characteristic                               | n                            | %  | n                            | %   | n                             | %   | n                      | %  |
| Sex                  | Male   | 8                            | 80 | 6                            | 60  | 3                             | 30  | 17                     | 57 |
|                      | Female                                       | 2                            | 20 | 4                            | 40  | 7                             | 70  | 13                     | 43 |
| Ethnicity            | Not Hispanic or Latino                       | 9                            | 90 | 9                            | 90  | 10                            | 100 | 28                     | 93 |
|                      | Hispanic or Latino                           | 1                            | 10 | 1                            | 10  | .                             | .   | 2                      | 7  |
|                      | Not Reported                                 | .                            | .  | .                            | .   | .                             | .   | .                      | .  |
|                      | Unknown                                      | .                            | .  | .                            | .   | .                             | .   | .                      | .  |
| Race                 | American Indian or<br>Alaska Native          | .                            | .  | .                            | .   | .                             | .   | .                      | .  |
|                      | Asian  | 1                            | 10 | .                            | .   | .                             | .   | 1                      | 3  |
|                      | Native Hawaiian or<br>other Pacific Islander | .                            | .  | .                            | .   | .                             | .   | .                      | .  |
|                      | Black  | .                            | .  | .                            | .   | .                             | .   | .                      | .  |
|                      | White  | 9                            | 90 | 10                           | 100 | 10                            | 100 | 29                     | 97 |
|                      | Multi Racial                                 | .                            | .  | .                            | .   | .                             | .   | .                      | .  |
|                      | Unknown                                      | .                            | .  | .                            | .   | .                             | .   | .                      | .  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 2D:**  
**Summary of Continuous Demographic and Baseline Characteristics**  
**by Vaccination Group - All Subjects 18-55 Years of Age**

|                               |                    | <b>25 µg<br/>mRNA-1273<br/>(N=15)</b> | <b>50 µg<br/>mRNA -1273<br/>(N=15)</b> | <b>100 µg<br/>mRNA -1273<br/>(N=15)</b> | <b>250 µg<br/>mRNA -1273<br/>(N=15)</b> | <b>All Subjects<br/>(N=60)</b> |
|-------------------------------|--------------------|---------------------------------------|--|---|---|--------------------------------|
| <b>Variable</b>               | <b>Statistic</b>   | <b>n</b>                              | <b>n</b>                               | <b>n</b>                                | <b>n</b>                                | <b>n</b>                       |
| <b>Age (Years)</b>            | Mean               | 36.7                                  | 37.0                                   | 31.3                                    | 31.0                                    | 34.0                           |
|                               | Standard Deviation | 7.9                                   | 10.0                                   | 8.7                                     | 8.0                                     | 8.9                            |
|                               | Median             | 35.9                                  | 34.6                                   | 31.6                                    | 30.3                                    | 32.1                           |
|                               | Minimum            | 25                                    | 22                                     | 20                                      | 18                                      | 18                             |
|                               | Maximum            | 53                                    | 54                                     | 53                                      | 50                                      | 54                             |
| <b>Height (cm)</b>            | Mean               | 175.70                                | 176.39                                 | 171.33                                  | 167.93                                  | 172.84                         |
|                               | Standard Deviation | 9.18                                  | 8.73                                   | 7.32                                    | 11.25                                   | 9.64                           |
|                               | Median             | 174.50                                | 178.60                                 | 170.00                                  | 165.10                                  | 172.70                         |
|                               | Minimum            | 158.7                                 | 162.6                                  | 160.7                                   | 152.7                                   | 152.7                          |
|                               | Maximum            | 194.1                                 | 188.8                                  | 188.0                                   | 185.7                                   | 194.1                          |
| <b>Weight (kg)</b>            | Mean               | 76.44                                 | 72.55                                  | 78.67                                   | 70.10                                   | 74.44                          |
|                               | Standard Deviation | 14.86                                 | 15.05                                  | 10.69                                   | 13.70                                   | 13.75                          |
|                               | Median             | 72.20                                 | 73.00                                  | 78.50                                   | 74.10                                   | 73.90                          |
|                               | Minimum            | 56.2                                  | 50.9                                   | 54.2                                    | 52.1                                    | 50.9                           |
|                               | Maximum            | 107.9                                 | 108.0                                  | 98.7                                    | 95.9                                    | 108.0                          |
| <b>BMI (kg/m<sup>2</sup>)</b> | Mean               | 24.62                                 | 23.12                                  | 26.73                                   | 24.68                                   | 24.79                          |
|                               | Standard Deviation | 3.45                                  | 3.16                                   | 2.60                                    | 3.09                                    | 3.28                           |
|                               | Median             | 24.50                                 | 22.60                                  | 27.40                                   | 23.70                                   | 24.45                          |
|                               | Minimum            | 21.1                                  | 18.5                                   | 20.4                                    | 20.4                                    | 18.5                           |
|                               | Maximum            | 32.6                                  | 30.3                                   | 31.5                                    | 29.4                                    | 32.6                           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 2E:**  
**Summary of Continuous Demographic and Baseline Characteristics**  
**by Vaccination Group - All Subjects 56-70 Years of Age**

|                               |                    | <b>25 µg<br/>mRNA-1273<br/>(N=10)</b> | <b>50 µg<br/>mRNA-1273<br/>(N=10)</b> | <b>100 µg<br/>mRNA-1273<br/>(N=10)</b> | <b>All Subjects<br/>(N=30)</b> |
|-------------------------------|--------------------|---------------------------------------|---------------------------------------|--|--------------------------------|
| <b>Variable</b>               | <b>Statistic</b>   | <b>n</b>                              | <b>n</b>                              | <b>n</b>                               | <b>n</b>                       |
| <b>Age (Years)</b>            | Mean               | 65.8                                  | 62.1                                  | 63.8                                   | 63.9                           |
|                               | Standard Deviation | 4.5                                   | 3.7                                   | 4.3                                    | 4.3                            |
|                               | Median             | 67.0                                  | 61.6                                  | 64.5                                   | 65.0                           |
|                               | Minimum            | 56                                    | 56                                    | 56                                     | 56                             |
|                               | Maximum            | 70                                    | 68                                    | 69                                     | 70                             |
| <b>Height (cm)</b>            | Mean               | 169.64                                | 173.62                                | 170.19                                 | 171.15                         |
|                               | Standard Deviation | 11.59                                 | 9.36                                  | 11.43                                  | 10.62                          |
|                               | Median             | 167.60                                | 177.00                                | 169.35                                 | 170.60                         |
|                               | Minimum            | 149.0                                 | 157.5                                 | 152.4                                  | 149.0                          |
|                               | Maximum            | 186.0                                 | 186.7                                 | 195.6                                  | 195.6                          |
| <b>Weight (kg)</b>            | Mean               | 73.47                                 | 71.05                                 | 69.40                                  | 71.31                          |
|                               | Standard Deviation | 12.77                                 | 11.75                                 | 13.62                                  | 12.40                          |
|                               | Median             | 70.45                                 | 71.90                                 | 65.60                                  | 69.45                          |
|                               | Minimum            | 52.0                                  | 52.0                                  | 50.5                                   | 50.5                           |
|                               | Maximum            | 89.8                                  | 87.0                                  | 95.2                                   | 95.2                           |
| <b>BMI (kg/m<sup>2</sup>)</b> | Mean               | 25.38                                 | 23.41                                 | 23.73                                  | 24.17                          |
|                               | Standard Deviation | 2.53                                  | 2.02                                  | 2.26                                   | 2.37                           |
|                               | Median             | 24.85                                 | 23.25                                 | 23.80                                  | 23.45                          |
|                               | Minimum            | 22.4                                  | 21.0                                  | 20.8                                   | 20.8                           |
|                               | Maximum            | 29.5                                  | 27.8                                  | 27.4                                   | 29.5                           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**TABLE 2F:**  
**Summary of Continuous Demographic and Baseline Characteristics**  
**by Vaccination Group - All Subjects  $\geq 71$  Years of Age**

|                               |                    | <b>25 µg<br/>mRNA-1273<br/>(N=10)</b> | <b>50 µg<br/>mRNA-1273<br/>(N=10)</b> | <b>100 µg<br/>mRNA-1273<br/>(N=10)</b> | <b>All Subjects<br/>(N=30)</b> |
|-------------------------------|--------------------|---------------------------------------|---------------------------------------|--|--------------------------------|
| <b>Variable</b>               | <b>Statistic</b>   | <b>n</b>                              | <b>n</b>                              | <b>n</b>                               | <b>n</b>                       |
| <b>Age (Years)</b>            | Mean               | 72.8                                  | 75.1                                  | 72.6                                   | 73.5                           |
|                               | Standard Deviation | 1.2                                   | 3.4                                   | 1.1                                    | 2.4                            |
|                               | Median             | 72.6                                  | 73.6                                  | 72.6                                   | 72.9                           |
|                               | Minimum            | 71                                    | 72                                    | 71                                     | 71                             |
|                               | Maximum            | 75                                    | 83                                    | 75                                     | 83                             |
| <b>Height (cm)</b>            | Mean               | 171.03                                | 171.97                                | 166.57                                 | 169.86                         |
|                               | Standard Deviation | 8.21                                  | 9.51                                  | 8.43                                   | 8.76                           |
|                               | Median             | 172.45                                | 170.00                                | 167.25                                 | 170.30                         |
|                               | Minimum            | 153.9                                 | 161.0                                 | 152.5                                  | 152.5                          |
|                               | Maximum            | 180.1                                 | 188.0                                 | 181.7                                  | 188.0                          |
| <b>Weight (kg)</b>            | Mean               | 72.95                                 | 72.86                                 | 72.16                                  | 72.66                          |
|                               | Standard Deviation | 13.81                                 | 9.37                                  | 10.89                                  | 11.11                          |
|                               | Median             | 78.30                                 | 73.05                                 | 69.80                                  | 74.45                          |
|                               | Minimum            | 47.4                                  | 56.3                                  | 57.9                                   | 47.4                           |
|                               | Maximum            | 87.6                                  | 86.2                                  | 91.2                                   | 91.2                           |
| <b>BMI (kg/m<sup>2</sup>)</b> | Mean               | 24.76                                 | 24.66                                 | 26.02                                  | 25.15                          |
|                               | Standard Deviation | 3.53                                  | 2.72                                  | 3.52                                   | 3.22                           |
|                               | Median             | 25.80                                 | 24.60                                 | 26.70                                  | 25.35                          |
|                               | Minimum            | 19.9                                  | 20.7                                  | 20.1                                   | 19.9                           |
|                               | Maximum            | 29.2                                  | 29.1                                  | 29.7                                   | 29.7                           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 2G:**  
**Study Status: Number of Subjects Completing Study Milestones**

|  | Day 1          | Day 2           | Day 3           | Day 8                  | Day 15                 | Day 29         | Day 30          | Day 31          |
|--|----------------|-----------------|-----------------|------------------------|------------------------|----------------|-----------------|-----------------|
| Study Group  | Vaccination 1  | Phone Follow-up | Phone Follow-up | Clinic Visit Follow-Up | Clinic Visit Follow-Up | Vaccination 2  | Phone Follow-up | Phone Follow-up |
| 25 µg (18-55 years)  | 15/15 (100%)   | 15/15 (100%)    | 15/15 (100%)    | 15/15 (100%)           | 15/15 (100%)           | 15/15 (100%)   | 13/15 (87%)     | 13/15 (87%)     |
| 50 µg (18-55 years)  | 15/15 (100%)   | 15/15 (100%)    | 15/15 (100%)    | 15/15 (100%)           | 15/15 (100%)           | 15/15 (100%)   | 15/15 (100%)    | 15/15 (100%)    |
| 100 µg (18-55 years)   | 15/15 (100%)   | 15/15 (100%)    | 15/15 (100%)    | 15/15 (100%)           | 15/15 (100%)           | 15/15 (100%)   | 15/15 (100%)    | 15/15 (100%)    |
| 250 µg (18-55 years)   | 15/15 (100%)   | 15/15 (100%)    | 15/15 (100%)    | 15/15 (100%)           | 15/15 (100%)           | 15/15 (100%)   | 14/15 (93%)     | 14/15 (93%)     |
| 25 µg (56-70 years)  | 10/10 (100%)   | 10/10 (100%)    | 10/10 (100%)    | 10/10 (100%)           | 10/10 (100%)           | 10/10 (100%)   | 10/10 (100%)    | 10/10 (100%)    |
| 50 µg (56-70 years)  | 10/10 (100%)   | 10/10 (100%)    | 10/10 (100%)    | 10/10 (100%)           | 10/10 (100%)           | 10/10 (100%)   | 10/10 (100%)    | 10/10 (100%)    |
| 100 µg (56-70 years)   | 10/10 (100%)   | 10/10 (100%)    | 10/10 (100%)    | 10/10 (100%)           | 10/10 (100%)           | 10/10 (100%)   | 9/10 (90%)      | 9/10 (90%)      |
| 25 µg (≥71 years)  | 10/10 (100%)   | 10/10 (100%)    | 10/10 (100%)    | 10/10 (100%)           | 10/10 (100%)           | 10/10 (100%)   | 10/10 (100%)    | 10/10 (100%)    |
| 50 µg (≥71 years)  | 10/10 (100%)   | 10/10 (100%)    | 10/10 (100%)    | 10/10 (100%)           | 10/10 (100%)           | 10/10 (100%)   | 10/10 (100%)    | 10/10 (100%)    |
| 100 µg (≥71 years)   | 10/10 (100%)   | 10/10 (100%)    | 10/10 (100%)    | 10/10 (100%)           | 10/10 (100%)           | 10/10 (100%)   | 10/10 (100%)    | 10/10 (100%)    |
| All Subjects   | 120/120 (100%) | 120/120 (100%)  | 120/120 (100%)  | 120/120 (100%)         | 120/120 (100%)         | 120/120 (100%) | 116/120 (97%)   | 116/120 (97%)   |
| Note: Percentages reflective of ongoing status of the trial. |                |                 |                 |                        |                        |                |                 |                 |

|                      | Day 36                 | Day 43                 | Day 57                 | Day 119                | Day 209                | Day 394           |
|----------------------|------------------------|------------------------|------------------------|------------------------|------------------------|-------------------|
| Study Group          | Clinic Visit Follow-Up | Clinic Visit Follow-Up | Clinic Visit Follow-Up | Clinic Visit Follow-Up | Clinic Visit Follow-Up | Final Study Visit |
| 25 µg (18-55 years)  | 15/15 (100%)           | 15/15 (100%)           | 15/15 (100%)           | 15/15 (100%)           | 1/15 (7%)              | 0/15 (0%)         |
| 50 µg (18-55 years)  | 15/15 (100%)           | 15/15 (100%)           | 15/15 (100%)           | 11/15 (73%)            | 0/15 (0%)              | 0/15 (0%)         |
| 100 µg (18-55 years) | 15/15 (100%)           | 15/15 (100%)           | 15/15 (100%)           | 15/15 (100%)           | 2/15 (13%)             | 0/15 (0%)         |
| 250 µg (18-55 years) | 15/15 (100%)           | 15/15 (100%)           | 15/15 (100%)           | 15/15 (100%)           | 0/15 (0%)              | 0/15 (0%)         |
| 25 µg (56-70 years)  | 10/10 (100%)           | 10/10 (100%)           | 10/10 (100%)           | 10/10 (100%)           | 0/10 (0%)              | 0/10 (0%)         |
| 50 µg (56-70 years)  | 10/10 (100%)           | 10/10 (100%)           | 10/10 (100%)           | 10/10 (100%)           | 0/10 (0%)              | 0/10 (0%)         |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 2G:**  
**Study Status: Number of Subjects Completing Study Milestones** (*continued*)

|  | Day 36                    | Day 43                    | Day 57                    | Day 119                   | Day 209                   | Day 394                 |
|--|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|-------------------------|
| Study Group  | Clinic Visit<br>Follow-Up | Clinic Visit<br>Follow-Up | Clinic Visit<br>Follow-Up | Clinic Visit<br>Follow-Up | Clinic Visit<br>Follow-Up | Final<br>Study<br>Visit |
| 100 µg (56-70 years)   | 10/10 (100%)              | 10/10 (100%)              | 10/10 (100%)              | 10/10 (100%)              | 0/10 (0%)                 | 0/10 (0%)               |
| 25 µg (≥71 years)  | 10/10 (100%)              | 10/10 (100%)              | 10/10 (100%)              | 10/10 (100%)              | 0/10 (0%)                 | 0/10 (0%)               |
| 50 µg (≥71 years)  | 10/10 (100%)              | 10/10 (100%)              | 10/10 (100%)              | 10/10 (100%)              | 0/10 (0%)                 | 0/10 (0%)               |
| 100 µg (≥71 years)   | 10/10 (100%)              | 10/10 (100%)              | 10/10 (100%)              | 10/10 (100%)              | 0/10 (0%)                 | 0/10 (0%)               |
| All Subjects   | 120/120 (100%)            | 120/120 (100%)            | 120/120 (100%)            | 116/120 (97%)             | 3/120 (3%)                | 0/120 (0%)              |
| Note: Percentages reflective of ongoing status of the trial. |                           |                           |                           |                           |                           |                         |

**TABLE 2H:**  
**Subject Disposition Vaccination Group - All Subjects 18-55 Years of Age**

|   | 25 µg<br>mRNA-1273<br>(N=15) |     | 50 µg<br>mRNA -1273<br>(N=15) |     | 100 µg<br>mRNA -1273<br>(N=15) |     | 250 µg<br>mRNA -1273<br>(N=15) |     | All Subjects<br>(N=60) |     |
|---|------------------------------|-----|-------------------------------|-----|--------------------------------|-----|--------------------------------|-----|------------------------|-----|
| Subject Disposition   | n                            | %   | n                             | %   | n                              | %   | n                              | %   | n                      | %   |
| Screened  | .                            | .   | .                             | .   | .                              | .   | .                              | .   | .                      | .   |
| Enrolled  | 15                           | 100 | 15                            | 100 | 15                             | 100 | 15                             | 100 | 60                     | 100 |
| Received the first vaccination  | 15                           | 100 | 15                            | 100 | 15                             | 100 | 15                             | 100 | 60                     | 100 |
| Discontinued treatment <sup>a</sup>   | 2                            | 13  | .                             | .   | .                              | .   | 1                              | 7   | 3                      | 5   |
| Received the second vaccination   | 13                           | 87  | 15                            | 100 | 15                             | 100 | 14                             | 93  | 57                     | 95  |
| Discontinued treatment <sup>a</sup>   | 2                            | 13  | .                             | .   | .                              | .   | 1                              | 7   | 3                      | 5   |
| Study ongoing   | 15                           | 100 | 15                            | 100 | 15                             | 100 | 15                             | 100 | 60                     | 100 |
| Early termination <sup>a</sup>  | .                            | .   | .                             | .   | .                              | .   | .                              | .   | .                      | .   |
| Completed study   | .                            | .   | .                             | .   | .                              | .   | .                              | .   | .                      | .   |
| <sup>a</sup> Refer to <a href="#">Table 2K</a> for reasons subjects discontinued or terminated early. |                              |     |                               |     |                                |     |                                |     |                        |     |

**TABLE 2I:**  
**Subject Disposition Vaccination Group - All Subjects 56-70 Years of Age**

|   | 25 µg<br>mRNA-1273<br>(N=10) |     | 50 µg<br>mRNA-1273<br>(N=10) |     | 100 µg<br>mRNA-1273<br>(N=10) |     | All Subjects<br>(N=30) |     |
|---|------------------------------|-----|------------------------------|-----|-------------------------------|-----|------------------------|-----|
| Subject Disposition   | n                            | %   | n                            | %   | n                             | %   | n                      | %   |
| Screened  | .                            | .   | .                            | .   | .                             | .   | .                      | .   |
| Enrolled  | 10                           | 100 | 10                           | 100 | 10                            | 100 | 30                     | 100 |
| Received the first vaccination  | 10                           | 100 | 10                           | 100 | 10                            | 100 | 30                     | 100 |
| Discontinued treatment <sup>a</sup>   | .                            | .   | .                            | .   | 1                             | 10  | 1                      | 3   |
| Received the second vaccination   | 10                           | 100 | 10                           | 100 | 9                             | 90  | 29                     | 97  |
| Discontinued treatment <sup>a</sup>   | .                            | .   | .                            | .   | 1                             | 10  | 1                      | 3   |
| Study ongoing   | 10                           | 100 | 10                           | 100 | 10                            | 100 | 30                     | 100 |
| Early termination <sup>a</sup>  | .                            | .   | .                            | .   | .                             | .   | .                      | .   |
| Completed study   | .                            | .   | .                            | .   | .                             | .   | .                      | .   |
| <sup>a</sup> Refer to <a href="#">Table 2K</a> for reasons subjects discontinued or terminated early. |                              |     |                              |     |                               |     |                        |     |

**TABLE 2J:**  
**Subject Disposition Vaccination Group - All Subjects  $\geq$  71 Years of Age**

|   | 25 µg<br>mRNA-1273<br>(N=10) |     | 50 µg<br>mRNA-1273<br>(N=10) |     | 100 µg<br>mRNA-1273<br>(N=10) |     | All Subjects<br>(N=30) |     |
|---|------------------------------|-----|------------------------------|-----|-------------------------------|-----|------------------------|-----|
| Subject Disposition   | n                            | %   | n                            | %   | n                             | %   | n                      | %   |
| Screened  | .                            | .   | .                            | .   | .                             | .   | .                      | .   |
| Enrolled  | 10                           | 100 | 10                           | 100 | 10                            | 100 | 30                     | 100 |
| Received the first vaccination  | 10                           | 100 | 10                           | 100 | 10                            | 100 | 30                     | 100 |
| Discontinued treatment <sup>a</sup>   | .                            | .   | .                            | .   | .                             | .   | .                      | .   |
| Received the second vaccination   | 10                           | 100 | 10                           | 100 | 10                            | 100 | 30                     | 100 |
| Discontinued treatment <sup>a</sup>   | .                            | .   | .                            | .   | .                             | .   | .                      | .   |
| Study ongoing   | 10                           | 100 | 10                           | 100 | 10                            | 100 | 30                     | 100 |
| Early termination <sup>a</sup>  | .                            | .   | .                            | .   | .                             | .   | .                      | .   |
| Completed study   | .                            | .   | .                            | .   | .                             | .   | .                      | .   |
| <sup>a</sup> Refer to <a href="#">Table 2K</a> for reasons subjects discontinued or terminated early. |                              |     |                              |     |                               |     |                        |     |

**TABLE 2K:**  
**Early Terminations or Discontinued Subjects**

|            |                         |                 | Treatment Discontinuation   |                                 | Early Termination        |                  |                              |                                |
|------------|-------------------------|-----------------|---|---------------------------------|--------------------------|------------------|------------------------------|--------------------------------|
| Subject ID | Vaccination Group       | Enrollment Date | Reason for Treatment Discontinuation  | Number of Vaccinations Received | Subject Terminated Early | Termination Date | Reason for Early Termination | Length of Time on Study (days) |
| CV01KP018  | 25 µg<br>(18-55 years)  | 03/24/20        | Became ineligible after enrollment, specify and enter eligibility criterion # Exclusion 22 (Subject has been exposed (b) (6) to someone with SARS-CoV-2 infection.) | 1                               | No                       | -                | -                            | -                              |
| CV01KP028  | 25 µg<br>(18-55 years)  | 03/24/20        | Adverse event, other than serious adverse event, specify AE # 2 (HIVES ON LOWER EXTREMITIES)  | 1                               | No                       | -                | -                            | -                              |
| CV01KP037  | 250 µg<br>(18-55 years) | 04/08/20        | Adverse event, other than serious adverse event, specify AE # 2 (SORE THROAT)   | 1                               | No                       | -                | -                            | -                              |
| CV01EM045  | 100 µg<br>(56-70 years) | 04/23/20        | Adverse event, other than serious adverse event, specify AE # 2 (MACULOPAPULAR RASH)  | 1                               | No                       | -                | -                            | -                              |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 3A:**  
**Listing of Serious Adverse Events**

**No serious adverse events have been reported.**



**TABLE 3B:**  
**Listing of MAAEs and NOCMCs**

| Subject ID | Vaccination Group       | Event Description         | Number of Doses Received at Time of Event | Date of Product Administration <sup>a</sup> | Duration of Event | Date of Onset | MedDRA <sup>®</sup> Sytem Organ Class    | MAAEs | NOCMCs | Relationship <sup>b</sup> | Outcome               |
|------------|-------------------------|---------------------------|---|---|-------------------|---------------|--|-------|--------|---------------------------|-----------------------|
| CV01EM010  | 100 µg<br>(18-55 years) | Gastroenteritis           | 02  | 24APR2020                                   | 78 (1)            | 11JUL2020     | Infections and infestations              | Yes   | No     | Not related               | Recovered /resolved   |
| CV01EM010  | 100 µg<br>(18-55 years) | Worsening ADHD Symptoms   | 02  | 24APR2020                                   | 21 (61)           | 15MAY2020     | Psychiatric disorders                    | Yes   | No     | Not related               | Recovered /resolved   |
| CV01EM012  | 100 µg<br>(18-55 years) | Infected Cyst             | 02  | 24APR2020                                   | 61 (9)            | 24JUN2020     | Infections and infestations              | Yes   | No     | Not related               | Recovered /resolved   |
| CV01EM016  | 250 µg<br>(18-55 years) | Worsening Vaginal Itching | 01  | 14APR2020                                   | 6 (34)            | 20APR2020     | Reproductive system and breast disorders | Yes   | No     | Not related               | Recovered /resolved   |
| CV01EM020  | 250 µg<br>(18-55 years) | Abdominal Discomfort      | 02  | 12MAY2020                                   | 26 (10)           | 07JUN2020     | Gastrointestinal disorders               | Yes   | No     | Related                   | Recovered /resolved   |
| CV01EM025  | 25 µg<br>(56-70 years)  | Worsening Toenail Fungus  | 01  | 20APR2020                                   | 25 (Ongoing)      | 15MAY2020     | Infections and infestations              | Yes   | No     | Not related               | Recovering /resolving |
| CV01EM029  | 25 µg<br>(56-70 years)  | Decreased Bone Density    | 02  | 18MAY2020                                   | 28 (Ongoing)      | 15JUN2020     | Investigations                           | Yes   | Yes    | Not related               | Recovering /resolving |
| CV01EM029  | 25 µg<br>(56-70 years)  | Worsening of Sciatica     | 02  | 18MAY2020                                   | 56 (39)           | 13JUL2020     | Nervous system disorders                 | Yes   | No     | Not related               | Recovered /resolved   |
| CV01EM045  | 100 µg<br>(56-70 years) | Paronychia                | 01  | 23APR2020                                   | 2 (13)            | 25APR2020     | Infections and infestations              | Yes   | No     | Not related               | Recovered /resolved   |
| CV01EM045  | 100 µg<br>(56-70 years) | Contact Dermatitis        | 01  | 23APR2020                                   | 111 (26)          | 12AUG2020     | Skin and subcutaneous tissue disorders   | Yes   | No     | Not related               | Recovered /resolved   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 3B:**  
**Listing of MAAEs and NOCMCs** (*continued*)

| Subject ID | Vaccination Group       | Event Description      | Number of Doses Received at Time of Event | Date of Product Administration <sup>a</sup> | Duration of Event | Date of Onset | MedDRA <sup>®</sup> Sytem Organ Class           | MAAEs | NOCMCs | Relationship <sup>b</sup> | Outcome             |
|------------|-------------------------|------------------------|---|---|-------------------|---------------|---|-------|--------|---------------------------|---------------------|
| CV01EM045  | 100 µg<br>(56-70 years) | Maculopapular Rash     | 01  | 23APR2020                                   | 9 (21)            | 02MAY2020     | Skin and subcutaneous tissue disorders          | Yes   | No     | Not related               | Recovered /resolved |
| CV01EM053  | 50 µg<br>(18-55 years)  | Abdominal Pain         | 01  | 04JUN2020                                   | 17 (3)            | 21JUN2020     | Gastrointestinal disorders                      | Yes   | No     | Not related               | Recovered /resolved |
| CV01KP005  | 25 µg<br>(18-55 years)  | Hordeolum Exacerbation | 02  | 14APR2020                                   | 55 (Ongoing)      | 08JUN2020     | Infections and infestations                     | Yes   | No     | Not related               |                     |
| CV01KP005  | 25 µg<br>(18-55 years)  | Jaw Pain               | 02  | 14APR2020                                   | 36 (61)           | 20MAY2020     | Musculoskeletal and connective tissue disorders | Yes   | No     | Not related               | Recovered /resolved |
| CV01KP006  | 25 µg<br>(18-55 years)  | Infected Pustules      | 02  | 14APR2020                                   | 47 (42)           | 31MAY2020     | Infections and infestations                     | Yes   | No     | Not related               | Recovered /resolved |
| CV01KP011  | 25 µg<br>(18-55 years)  | Contusions             | 02  | 21APR2020                                   | 74 (12)           | 04JUL2020     | Injury, poisoning and procedural complications  | Yes   | No     | Not related               | Recovered /resolved |
| CV01KP031  | 25 µg<br>(18-55 years)  | Puncture Wound         | 02  | 21APR2020                                   | 72 (26)           | 02JUL2020     | Injury, poisoning and procedural complications  | Yes   | No     | Not related               | Recovered /resolved |
| CV01KP037  | 250 µg<br>(18-55 years) | Anal Fissure           | 01  | 08APR2020                                   | 56 (21)           | 03JUN2020     | Gastrointestinal disorders                      | Yes   | No     | Not related               | Recovered /resolved |
| CV01KP037  | 250 µg<br>(18-55 years) | UTI                    | 01  | 08APR2020                                   | 133 (2)           | 19AUG2020     | Infections and infestations                     | Yes   | No     | Not related               | Recovered /resolved |
| CV01KP037  | 250 µg<br>(18-55 years) | Vaginal Itching        | 01  | 08APR2020                                   | 56 (18)           | 03JUN2020     | Reproductive system and breast disorders        | Yes   | No     | Not related               | Recovered /resolved |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 3B:**  
**Listing of MAAEs and NOCMCs** (*continued*)

| Subject ID | Vaccination Group       | Event Description                     | Number of Doses Received at Time of Event | Date of Product Administration <sup>a</sup> | Duration of Event | Date of Onset | MedDRA <sup>®</sup> Sytem Organ Class                               | MAAEs | NOCMCs | Relationship <sup>b</sup> | Outcome             |
|------------|-------------------------|---------------------------------------|---|---|-------------------|---------------|---|-------|--------|---------------------------|---------------------|
| CV01KP037  | 250 µg<br>(18-55 years) | Sore Throat                           | 01  | 08APR2020                                   | 24 (3)            | 02MAY2020     | Respiratory, thoracic and mediastinal disorders                     | Yes   | No     | Not related               | Recovered /resolved |
| CV01KP040  | 250 µg<br>(18-55 years) | Epididymitis                          | 02  | 05MAY2020                                   | 29 (16)           | 03JUN2020     | Infections and infestations   | Yes   | No     | Not related               | Recovered /resolved |
| CV01KP067  | 100 µg<br>(≥71 years)   | Chipped Tooth                         | 02  | 02JUN2020                                   | 3 (76)            | 05JUN2020     | Injury, poisoning and procedural complications                      | Yes   | No     | Not related               | Recovered /resolved |
| CV01KP068  | 25 µg<br>(≥71 years)    | Exacerbation of Arthritis             | 01  | 05MAY2020                                   | 27 (62)           | 01JUN2020     | Musculoskeletal and connective tissue disorders                     | Yes   | No     | Not related               | Recovered /resolved |
| CV01KP077  | 100 µg<br>(≥71 years)   | UTI                                   | 02  | 08JUN2020                                   | 58 (3)            | 05AUG2020     | Infections and infestations   | Yes   | No     | Not related               | Recovered /resolved |
| CV01KP081  | 100 µg<br>(≥71 years)   | Squamous Cell Carcinoma               | 02  | 08JUN2020                                   | 79 (0)            | 26AUG2020     | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Yes   | No     | Not related               | Recovered /resolved |
| CV01KP094  | 50 µg<br>(18-55 years)  | Vertigo                               | 02  | 13JUL2020                                   | 77 (0)            | 28SEP2020     | Ear and labyrinth disorders   | Yes   | No     | Not related               | Recovered /resolved |
| CV01KP096  | 50 µg<br>(18-55 years)  | Exacerbation of Impacted Wisdom Teeth | 02  | 13JUL2020                                   | 2 (5)             | 15JUL2020     | Gastrointestinal disorders  | Yes   | No     | Not related               | Recovered /resolved |
| CV01VR002  | 50 µg<br>(≥71 years)    | Traumatic Injuries                    | 01  | 05JUN2020                                   | 19 (21)           | 24JUN2020     | Injury, poisoning and procedural complications                      | Yes   | No     | Not related               | Recovered /resolved |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 3B:**  
**Listing of MAAEs and NOCMCs** (*continued*)

| Subject ID  | Vaccination Group      | Event Description       | Number of Doses Received at Time of Event | Date of Product Administration <sup>a</sup> | Duration of Event | Date of Onset | MedDRA <sup>®</sup> Sytem Organ Class          | MAAEs | NOCMCs | Relationship <sup>b</sup> | Outcome               |
|---|------------------------|-------------------------|---|---|-------------------|---------------|--|-------|--------|---------------------------|-----------------------|
| CV01VR002   | 50 µg<br>(≥71 years)   | Tick Bite               | 02  | 01JUL2020                                   | 35 (22)           | 05AUG2020     | Injury, poisoning and procedural complications | Yes   | No     | Not related               | Recovered /resolved   |
| CV01VR003   | 50 µg<br>(56-70 years) | Viral Syndrome          | 02  | 02JUL2020                                   | 40 (27)           | 11AUG2020     | Infections and infestations                    | Yes   | No     | Not related               | Recovered /resolved   |
| CV01VR005   | 50 µg<br>(56-70 years) | Cracked Tooth           | 02  | 30JUN2020                                   | 80 (Ongoing)      | 18SEP2020     | Injury, poisoning and procedural complications | Yes   | No     | Not related               | Recovering /resolving |
| CV01VR028   | 50 µg<br>(56-70 years) | Urinary Tract Infection | 02  | 30JUN2020                                   | 31 (40)           | 31JUL2020     | Infections and infestations                    | Yes   | No     | Not related               | Recovered /resolved   |
| <sup>a</sup> Date of most recent dose/product administration.<br><sup>b</sup> Related, Not Related. |                        |                         |   |   |                   |               |  |       |        |                           |                       |

**TABLE 4A(i):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship,**  
**and Vaccination Group – 25 mcg mRNA-1273 18-55 years (N=15)**

| System Organ Class (SOC)                             | Preferred Term (PT)         | Total Events (n) | Severity |              |            | Relationship to Study Vaccination |             |                        |
|--|-----------------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
|  |                             |                  | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| Any SOC  | Any PT                      | 31               | 28       | 3            | -          | 26                                | 5           | -                      |
| Gastrointestinal disorders                           | Any PT                      | 4                | 2        | 2            | -          | 3                                 | 1           | -                      |
|  | Flatulence                  | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Vomiting                    | 3                | 1        | 2            | -          | 2                                 | 1           | -                      |
| General disorders and administration site conditions | Any PT                      | 6                | 6        | -            | -          | 6                                 | -           | -                      |
|  | Fatigue                     | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Injection site irritation   | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Vessel puncture site bruise | 4                | 4        | -            | -          | 4                                 | -           | -                      |
| Infections and infestations                          | Any PT                      | 2                | 1        | 1            | -          | 2                                 | -           | -                      |
|  | Hordeolum                   | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|  | Pustule                     | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Injury, poisoning and procedural complications       | Any PT                      | 8                | 8        | -            | -          | 8                                 | -           | -                      |
|  | Contusion                   | 3                | 3        | -            | -          | 3                                 | -           | -                      |
|  | Muscle strain               | 2                | 2        | -            | -          | 2                                 | -           | -                      |
|  | Skin abrasion               | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Skin laceration             | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Wound                       | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Musculoskeletal and connective tissue disorders      | Any PT                      | 2                | 2        | -            | -          | 1                                 | 1           | -                      |
|  | Muscular weakness           | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|  | Pain in jaw                 | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Nervous system disorders                             | Presyncope                  | 1                | 1        | -            | -          | 1                                 | -           | -                      |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4A(i):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 25 mcg mRNA-1273 18-55 years (N=15) (continued)**

| System Organ Class (SOC)                           | Preferred Term (PT)   | Total Events<br>(n) | Severity    |                 |               | Relationship to Study Vaccination |                |                           |
|--|-----------------------|---------------------|-------------|-----------------|---------------|-----------------------------------|----------------|---------------------------|
|  |                       |                     | Mild<br>(n) | Moderate<br>(n) | Severe<br>(n) | Not Related<br>(n)                | Related<br>(n) | Not Yet Determined<br>(n) |
| Respiratory, thoracic and<br>mediastinal disorders | Any PT                | 3                   | 3           | -               | -             | 2                                 | 1              | -                         |
|  | Dyspnoea exertional   | 1                   | 1           | -               | -             | 1                                 | -              | -                         |
|  | Oropharyngeal pain    | 2                   | 2           | -               | -             | 1                                 | 1              | -                         |
| Skin and subcutaneous tissue<br>disorders          | Any PT                | 4                   | 4           | -               | -             | 2                                 | 2              | -                         |
|  | Dermatitis contact    | 1                   | 1           | -               | -             | 1                                 | -              | -                         |
|  | Erythema              | 1                   | 1           | -               | -             | 1                                 | -              | -                         |
|  | Petechiae             | 1                   | 1           | -               | -             | -                                 | 1              | -                         |
|  | Urticaria             | 1                   | 1           | -               | -             | -                                 | 1              | -                         |
| Vascular disorders                                 | Systolic hypertension | 1                   | 1           | -               | -             | 1                                 | -              | -                         |

**TABLE 4A(ii):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship,**  
**and Vaccination Group – 50 mcg mRNA-1273 18-55 years (N=15)**

| System Organ Class (SOC)                             | Preferred Term (PT)                  | Total Events (n) | Severity |              |            | Relationship to Study Vaccination |             |                        |
|--|--------------------------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
|  |                                      |                  | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| Any SOC  | Any PT                               | 24               | 20       | 4            | -          | 17                                | 7           | -                      |
| Blood and lymphatic system disorders                 | Lymphadenopathy                      | 1                | 1        | -            | -          | -                                 | 1           | -                      |
| Cardiac disorders                                    | Bradycardia                          | 2                | 2        | -            | -          | 1                                 | 1           | -                      |
| Ear and labyrinth disorders                          | Vertigo                              | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Gastrointestinal disorders                           | Any PT                               | 4                | 1        | 3            | -          | 3                                 | 1           | -                      |
|  | Abdominal pain                       | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|  | Diarrhoea                            | 1                | -        | 1            | -          | -                                 | 1           | -                      |
|  | Dyspepsia                            | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Tooth impacted                       | 1                | -        | 1            | -          | 1                                 | -           | -                      |
| General disorders and administration site conditions | Any PT                               | 3                | 3        | -            | -          | 2                                 | 1           | -                      |
|  | Vaccination site movement impairment | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|  | Vessel puncture site bruise          | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Vessel puncture site haemorrhage     | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Immune system disorders                              | Seasonal allergy                     | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Infections and infestations                          | Upper respiratory tract infection    | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Injury, poisoning and procedural complications       | Skin abrasion                        | 2                | 2        | -            | -          | 2                                 | -           | -                      |
| Investigations                                       | Blood glucose decreased              | 1                | 1        | -            | -          | 1                                 | -           | -                      |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4A(ii):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 50 mcg mRNA-1273 18-55 years (N=15) (continued)**

| System Organ Class (SOC)                        | Preferred Term (PT)         | Total Events<br>(n) | Severity    |                 |               | Relationship to Study Vaccination |                |                           |
|---|-----------------------------|---------------------|-------------|-----------------|---------------|-----------------------------------|----------------|---------------------------|
|   |                             |                     | Mild<br>(n) | Moderate<br>(n) | Severe<br>(n) | Not Related<br>(n)                | Related<br>(n) | Not Yet Determined<br>(n) |
| Musculoskeletal and connective tissue disorders | Any PT                      | 2                   | 2           | -               | -             | 1                                 | 1              | -                         |
|   | Muscle spasms               | 1                   | 1           | -               | -             | -                                 | 1              | -                         |
|   | Myalgia                     | 1                   | 1           | -               | -             | 1                                 | -              | -                         |
| Respiratory, thoracic and mediastinal disorders | Any PT                      | 5                   | 4           | 1               | -             | 3                                 | 2              | -                         |
|   | Nasal congestion            | 2                   | 1           | 1               | -             | 1                                 | 1              | -                         |
|   | Oropharyngeal pain          | 1                   | 1           | -               | -             | 1                                 | -              | -                         |
|   | Upper-airway cough syndrome | 2                   | 2           | -               | -             | 1                                 | 1              | -                         |
| Skin and subcutaneous tissue disorders          | Rash                        | 1                   | 1           | -               | -             | 1                                 | -              | -                         |



**TABLE 4A(iii):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship,**  
**and Vaccination Group – 100 mcg mRNA-1273 18-55 years (N=15)**

| System Organ Class (SOC)                             | Preferred Term (PT)     | Total Events (n) | Severity |              |            | Relationship to Study Vaccination |             |                        |
|--|-------------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
|  |                         |                  | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| Any SOC  | Any PT                  | 28               | 22       | 6            | -          | 18                                | 10          | -                      |
| Cardiac disorders                                    | Bradycardia             | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Eye disorders  | Eye irritation          | 1                | 1        | -            | -          | -                                 | 1           | -                      |
| Gastrointestinal disorders                           | Any PT                  | 3                | 2        | 1            | -          | 2                                 | 1           | -                      |
|  | Abdominal discomfort    | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Abdominal pain          | 1                | -        | 1            | -          | -                                 | 1           | -                      |
|  | Faeces discoloured      | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| General disorders and administration site conditions | Any PT                  | 7                | 6        | 1            | -          | 3                                 | 4           | -                      |
|  | Feeling jittery         | 1                | -        | 1            | -          | -                                 | 1           | -                      |
|  | Injection site bruising | 3                | 3        | -            | -          | 3                                 | -           | -                      |
|  | Injection site pruritus | 3                | 3        | -            | -          | -                                 | 3           | -                      |
| Infections and infestations                          | Any PT                  | 2                | -        | 2            | -          | 2                                 | -           | -                      |
|  | Gastroenteritis         | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|  | Infected cyst           | 1                | -        | 1            | -          | 1                                 | -           | -                      |
| Injury, poisoning and procedural complications       | Any PT                  | 3                | 2        | 1            | -          | 3                                 | -           | -                      |
|  | Muscle strain           | 2                | 1        | 1            | -          | 2                                 | -           | -                      |
|  | Thermal burn            | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Investigations                                       | Heart rate increased    | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Metabolism and nutrition disorders                   | Decreased appetite      | 2                | 2        | -            | -          | -                                 | 2           | -                      |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4A(iii):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 100 mcg mRNA-1273 18-55 years (N=15) (continued)**

| System Organ Class (SOC)                        | Preferred Term (PT)                      | Total Events<br>(n) | Severity    |                 |               | Relationship to Study Vaccination |                |                           |
|---|--|---------------------|-------------|-----------------|---------------|-----------------------------------|----------------|---------------------------|
|   |  |                     | Mild<br>(n) | Moderate<br>(n) | Severe<br>(n) | Not Related<br>(n)                | Related<br>(n) | Not Yet Determined<br>(n) |
| Musculoskeletal and connective tissue disorders | Neck pain                                | 1                   | 1           | -               | -             | 1                                 | -              | -                         |
| Nervous system disorders                        | Dizziness                                | 1                   | 1           | -               | -             | 1                                 | -              | -                         |
| Psychiatric disorders                           | Attention deficit hyperactivity disorder | 1                   | -           | 1               | -             | 1                                 | -              | -                         |
| Reproductive system and breast disorders        | Breast pain                              | 1                   | 1           | -               | -             | 1                                 | -              | -                         |
| Respiratory, thoracic and mediastinal disorders | Any PT                                   | 3                   | 3           | -               | -             | 2                                 | 1              | -                         |
|   | Diaphragmatic spasm                      | 1                   | 1           | -               | -             | -                                 | 1              | -                         |
|   | Nasal congestion                         | 1                   | 1           | -               | -             | 1                                 | -              | -                         |
|   | Oropharyngeal pain                       | 1                   | 1           | -               | -             | 1                                 | -              | -                         |
| Vascular disorders                              | Vasodilatation                           | 1                   | 1           | -               | -             | -                                 | 1              | -                         |

**TABLE 4A(iv):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship,**  
**and Vaccination Group – 250 mcg mRNA-1273 18-55 years (N=15)**

| System Organ Class (SOC)                             | Preferred Term (PT)         | Total Events (n) | Severity |              |            | Relationship to Study Vaccination |             |                        |
|--|-----------------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
|  |                             |                  | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| Any SOC  | Any PT                      | 40               | 24       | 14           | 2          | 21                                | 19          | -                      |
| Cardiac disorders                                    | Bradycardia                 | 2                | 2        | -            | -          | 2                                 | -           | -                      |
| Eye disorders  | Scintillating scotoma       | 1                | 1        | -            | -          | -                                 | 1           | -                      |
| Gastrointestinal disorders                           | Any PT                      | 6                | 5        | 1            | -          | 3                                 | 3           | -                      |
|  | Abdominal discomfort        | 1                | -        | 1            | -          | -                                 | 1           | -                      |
|  | Abdominal pain upper        | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|  | Anal fissure                | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Dyspepsia                   | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Lip disorder                | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Vomiting                    | 1                | 1        | -            | -          | -                                 | 1           | -                      |
| General disorders and administration site conditions | Any PT                      | 5                | 3        | 2            | -          | 1                                 | 4           | -                      |
|  | Injection site erythema     | 2                | 1        | 1            | -          | -                                 | 2           | -                      |
|  | Injection site pruritus     | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|  | Malaise                     | 1                | -        | 1            | -          | -                                 | 1           | -                      |
|  | Vessel puncture site bruise | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Infections and infestations                          | Any PT                      | 2                | 1        | 1            | -          | 2                                 | -           | -                      |
|  | Epididymitis                | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|  | Urinary tract infection     | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Metabolism and nutrition disorders                   | Any PT                      | 4                | 1        | 3            | -          | 1                                 | 3           | -                      |
|  | Decreased appetite          | 3                | 1        | 2            | -          | -                                 | 3           | -                      |
|  | Hypoglycaemia               | 1                | -        | 1            | -          | 1                                 | -           | -                      |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4A(iv):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 250 mcg mRNA-1273 18-55 years (N=15) (continued)**

| System Organ Class (SOC)                        | Preferred Term (PT)   | Total Events (n) | Severity |              |            | Relationship to Study Vaccination |             |                        |
|---|-----------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
|   |                       |                  | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| Musculoskeletal and connective tissue disorders | Any PT                | 4                | 2        | 2            | -          | 2                                 | 2           | -                      |
|   | Arthralgia            | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Muscle spasms         | 1                | -        | 1            | -          | -                                 | 1           | -                      |
|   | Muscle strain         | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|   | Pain in extremity     | 1                | 1        | -            | -          | -                                 | 1           | -                      |
| Nervous system disorders                        | Any PT                | 6                | 1        | 3            | 2          | 4                                 | 2           | -                      |
|   | Dizziness             | 1                | -        | -            | 1          | -                                 | 1           | -                      |
|   | Headache              | 4                | 1        | 3            | -          | 4                                 | -           | -                      |
|   | Syncope               | 1                | -        | -            | 1          | -                                 | 1           | -                      |
| Psychiatric disorders                           | Any PT                | 2                | 2        | -            | -          | 1                                 | 1           | -                      |
|   | Anxiety               | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|   | Insomnia              | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Reproductive system and breast disorders        | Any PT                | 3                | 3        | -            | -          | 2                                 | 1           | -                      |
|   | Vaginal haemorrhage   | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|   | Vulvovaginal pruritus | 2                | 2        | -            | -          | 2                                 | -           | -                      |
| Respiratory, thoracic and mediastinal disorders | Oropharyngeal pain    | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Skin and subcutaneous tissue disorders          | Any PT                | 2                | -        | 2            | -          | -                                 | 2           | -                      |
|   | Hyperhidrosis         | 1                | -        | 1            | -          | -                                 | 1           | -                      |
|   | Night sweats          | 1                | -        | 1            | -          | -                                 | 1           | -                      |
| Vascular disorders                              | Any PT                | 2                | 2        | -            | -          | 2                                 | -           | -                      |
|   | Hypertension          | 1                | 1        | -            | -          | 1                                 | -           | -                      |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4A(iv):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 250 mcg mRNA-1273 18-55 years (N=15) (continued)**

|                          |                     |                     | Severity    |                 |               | Relationship to Study Vaccination |                |                           |
|--------------------------|---------------------|---------------------|-------------|-----------------|---------------|-----------------------------------|----------------|---------------------------|
| System Organ Class (SOC) | Preferred Term (PT) | Total Events<br>(n) | Mild<br>(n) | Moderate<br>(n) | Severe<br>(n) | Not Related<br>(n)                | Related<br>(n) | Not Yet Determined<br>(n) |
|                          | Hypotension         | 1                   | 1           | -               | -             | 1                                 | -              | -                         |

**TABLE 4A(v):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group –mRNA-1273 All Subjects 18-55 years (N=60)**

| System Organ Class (SOC)             | Preferred Term (PT)   | Total Events (n) | Severity |              |            | Relationship to Study Vaccination |             |                        |
|--------------------------------------|-----------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
|                                      |                       |                  | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| Any SOC                              | Any PT                | 123              | 94       | 27           | 2          | 82                                | 41          | -                      |
| Blood and lymphatic system disorders | Lymphadenopathy       | 1                | 1        | -            | -          | -                                 | 1           | -                      |
| Cardiac disorders                    | Bradycardia           | 5                | 5        | -            | -          | 4                                 | 1           | -                      |
| Ear and labyrinth disorders          | Vertigo               | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Eye disorders                        | Any PT                | 2                | 2        | -            | -          | -                                 | 2           | -                      |
|                                      | Eye irritation        | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|                                      | Scintillating scotoma | 1                | 1        | -            | -          | -                                 | 1           | -                      |
| Gastrointestinal disorders           | Any PT                | 17               | 10       | 7            | -          | 11                                | 6           | -                      |
|                                      | Abdominal discomfort  | 2                | 1        | 1            | -          | 1                                 | 1           | -                      |
|                                      | Abdominal pain        | 2                | -        | 2            | -          | 1                                 | 1           | -                      |
|                                      | Abdominal pain upper  | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|                                      | Anal fissure          | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|                                      | Diarrhoea             | 1                | -        | 1            | -          | -                                 | 1           | -                      |
|                                      | Dyspepsia             | 2                | 2        | -            | -          | 2                                 | -           | -                      |
|                                      | Faeces discoloured    | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|                                      | Flatulence            | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|                                      | Lip disorder          | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|                                      | Tooth impacted        | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|                                      | Vomiting              | 4                | 2        | 2            | -          | 2                                 | 2           | -                      |
|                                      | Any PT                | 21               | 18       | 3            | -          | 12                                | 9           | -                      |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4A(v):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – mRNA-1273 All Subjects 18-55 years (N=60) (continued)**

| System Organ Class (SOC)                             | Preferred Term (PT)                  | Total Events (n) | Severity |              |            | Relationship to Study Vaccination |             |                        |
|--|--------------------------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
|  |                                      |                  | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| General disorders and administration site conditions | Fatigue                              | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Feeling jittery                      | 1                | -        | 1            | -          | -                                 | 1           | -                      |
|  | Injection site bruising              | 3                | 3        | -            | -          | 3                                 | -           | -                      |
|  | Injection site erythema              | 2                | 1        | 1            | -          | -                                 | 2           | -                      |
|  | Injection site irritation            | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Injection site pruritus              | 4                | 4        | -            | -          | -                                 | 4           | -                      |
|  | Malaise                              | 1                | -        | 1            | -          | -                                 | 1           | -                      |
|  | Vaccination site movement impairment | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|  | Vessel puncture site bruise          | 6                | 6        | -            | -          | 6                                 | -           | -                      |
|  | Vessel puncture site haemorrhage     | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Immune system disorders                              | Seasonal allergy                     | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Infections and infestations                          | Any PT                               | 7                | 3        | 4            | -          | 7                                 | -           | -                      |
|  | Epididymitis                         | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|  | Gastroenteritis                      | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|  | Hordeolum                            | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|  | Infected cyst                        | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|  | Pustule                              | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Upper respiratory tract infection    | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Urinary tract infection              | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Any PT                               | 13               | 12       | 1            | -          | 13                                | -           | -                      |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4A(v):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – mRNA-1273 All Subjects 18-55 years (N=60) (continued)**

| System Organ Class (SOC)                        | Preferred Term (PT)     | Total Events (n) | Severity |              |            | Relationship to Study Vaccination |             |                        |
|---|-------------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
|   |                         |                  | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| Injury, poisoning and procedural complications  | Contusion               | 3                | 3        | -            | -          | 3                                 | -           | -                      |
|   | Muscle strain           | 4                | 3        | 1            | -          | 4                                 | -           | -                      |
|   | Skin abrasion           | 3                | 3        | -            | -          | 3                                 | -           | -                      |
|   | Skin laceration         | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Thermal burn            | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Wound                   | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Investigations                                  | Any PT                  | 2                | 2        | -            | -          | 2                                 | -           | -                      |
|   | Blood glucose decreased | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Heart rate increased    | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Metabolism and nutrition disorders              | Any PT                  | 6                | 3        | 3            | -          | 1                                 | 5           | -                      |
|   | Decreased appetite      | 5                | 3        | 2            | -          | -                                 | 5           | -                      |
|   | Hypoglycaemia           | 1                | -        | 1            | -          | 1                                 | -           | -                      |
| Musculoskeletal and connective tissue disorders | Any PT                  | 9                | 7        | 2            | -          | 5                                 | 4           | -                      |
|   | Arthralgia              | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Muscle spasms           | 2                | 1        | 1            | -          | -                                 | 2           | -                      |
|   | Muscle strain           | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|   | Muscular weakness       | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|   | Myalgia                 | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Neck pain               | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Pain in extremity       | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|   | Pain in jaw             | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Nervous system disorders                        | Any PT                  | 8                | 3        | 3            | 2          | 6                                 | 2           | -                      |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**TABLE 4A(v):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – mRNA-1273 All Subjects 18-55 years (N=60) (continued)**

| System Organ Class (SOC)                        | Preferred Term (PT)                      | Total Events (n) | Severity |              |            | Relationship to Study Vaccination |             |                        |
|---|--|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
|   |  |                  | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
|   | Dizziness                                | 2                | 1        | -            | 1          | 1                                 | 1           | -                      |
|   | Headache                                 | 4                | 1        | 3            | -          | 4                                 | -           | -                      |
|   | Presyncope                               | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Syncope                                  | 1                | -        | -            | 1          | -                                 | 1           | -                      |
| Psychiatric disorders                           | Any PT                                   | 3                | 2        | 1            | -          | 2                                 | 1           | -                      |
|   | Anxiety                                  | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|   | Attention deficit hyperactivity disorder | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|   | Insomnia                                 | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Reproductive system and breast disorders        | Any PT                                   | 4                | 4        | -            | -          | 3                                 | 1           | -                      |
|   | Breast pain                              | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Vaginal haemorrhage                      | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|   | Vulvovaginal pruritus                    | 2                | 2        | -            | -          | 2                                 | -           | -                      |
| Respiratory, thoracic and mediastinal disorders | Any PT                                   | 12               | 11       | 1            | -          | 8                                 | 4           | -                      |
|   | Diaphragmatic spasm                      | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|   | Dyspnoea exertional                      | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Nasal congestion                         | 3                | 2        | 1            | -          | 2                                 | 1           | -                      |
|   | Oropharyngeal pain                       | 5                | 5        | -            | -          | 4                                 | 1           | -                      |
|   | Upper-airway cough syndrome              | 2                | 2        | -            | -          | 1                                 | 1           | -                      |
| Skin and subcutaneous tissue disorders          | Any PT                                   | 7                | 5        | 2            | -          | 3                                 | 4           | -                      |
|   | Dermatitis contact                       | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Erythema                                 | 1                | 1        | -            | -          | 1                                 | -           | -                      |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4A(v):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – mRNA-1273 All Subjects 18-55 years (N=60) (continued)**

|                          |                       |                  | Severity |              |            | Relationship to Study Vaccination |             |                        |
|--------------------------|-----------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
| System Organ Class (SOC) | Preferred Term (PT)   | Total Events (n) | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
|                          | Hyperhidrosis         | 1                | -        | 1            | -          | -                                 | 1           | -                      |
|                          | Night sweats          | 1                | -        | 1            | -          | -                                 | 1           | -                      |
|                          | Petechiae             | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|                          | Rash                  | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|                          | Urticaria             | 1                | 1        | -            | -          | -                                 | 1           | -                      |
| Vascular disorders       | Any PT                | 4                | 4        | -            | -          | 3                                 | 1           | -                      |
|                          | Hypertension          | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|                          | Hypotension           | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|                          | Systolic hypertension | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|                          | Vasodilatation        | 1                | 1        | -            | -          | -                                 | 1           | -                      |

**TABLE 4B(i):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 25 mcg mRNA-1273 56-70 years (N=10)**

| System Organ Class (SOC)                             | Preferred Term (PT)     | Total Events (n) | Severity |              |            | Relationship to Study Vaccination |             |                        |
|--|-------------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
|  |                         |                  | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| Any SOC  | Any PT                  | 13               | 7        | 6            | -          | 11                                | 2           | -                      |
| General disorders and administration site conditions | Injection site bruising | 2                | 2        | -            | -          | 2                                 | -           | -                      |
| Infections and infestations                          | Onychomycosis           | 1                | -        | 1            | -          | 1                                 | -           | -                      |
| Injury, poisoning and procedural complications       | Any PT                  | 2                | -        | 2            | -          | 2                                 | -           | -                      |
|  | Exposure via inhalation | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|  | Limb injury             | 1                | -        | 1            | -          | 1                                 | -           | -                      |
| Investigations                                       | Bone density decreased  | 1                | -        | 1            | -          | 1                                 | -           | -                      |
| Metabolism and nutrition disorders                   | Decreased appetite      | 1                | -        | 1            | -          | -                                 | 1           | -                      |
| Musculoskeletal and connective tissue disorders      | Pain in extremity       | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Nervous system disorders                             | Any PT                  | 3                | 2        | 1            | -          | 3                                 | -           | -                      |
|  | Headache                | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Sciatica                | 2                | 1        | 1            | -          | 2                                 | -           | -                      |
| Psychiatric disorders                                | Insomnia                | 1                | 1        | -            | -          | -                                 | 1           | -                      |
| Respiratory, thoracic and mediastinal disorders      | Oropharyngeal pain      | 1                | 1        | -            | -          | 1                                 | -           | -                      |

**TABLE 4B(ii):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 50 µg mRNA-1273 56-70 years (N=10)**

| System Organ Class (SOC)                       | Preferred Term (PT)     | Total Events (n) | Severity |              |            | Relationship to Study Vaccination |             |                        |
|--|-------------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
|  |                         |                  | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| Any SOC  | Any PT                  | 8                | 4        | 3            | 1          | 7                                 | 1           | -                      |
| Cardiac disorders                              | Bradycardia             | 2                | 2        | -            | -          | 2                                 | -           | -                      |
| Gastrointestinal disorders                     | Abdominal discomfort    | 1                | -        | 1            | -          | -                                 | 1           | -                      |
| Infections and infestations                    | Any PT                  | 2                | -        | 1            | 1          | 2                                 | -           | -                      |
|  | Urinary tract infection | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|  | Viral infection         | 1                | -        | -            | 1          | 1                                 | -           | -                      |
| Injury, poisoning and procedural complications | Any PT                  | 3                | 2        | 1            | -          | 3                                 | -           | -                      |
|  | Muscle strain           | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Skin laceration         | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Tooth fracture          | 1                | -        | 1            | -          | 1                                 | -           | -                      |

**TABLE 4B(iii):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 100 mcg mRNA-1273 56-70 years (N=10)**

| System Organ Class (SOC)                        | Preferred Term (PT)   | Total Events (n) | Severity |              |            | Relationship to Study Vaccination |             |                        |
|---|-----------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
|   |                       |                  | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| Any SOC   | Any PT                | 11               | 6        | 4            | 1          | 10                                | 1           | -                      |
| Ear and labyrinth disorders                     | Vertigo               | 1                | 1        | -            | -          | -                                 | 1           | -                      |
| Gastrointestinal disorders                      | Haemorrhoids          | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Infections and infestations                     | Paronychia            | 1                | -        | 1            | -          | 1                                 | -           | -                      |
| Injury, poisoning and procedural complications  | Arthropod sting       | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Metabolism and nutrition disorders              | Hypoglycaemia         | 1                | -        | -            | 1          | 1                                 | -           | -                      |
| Nervous system disorders                        | Dizziness             | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Respiratory, thoracic and mediastinal disorders | Any PT                | 2                | 1        | 1            | -          | 2                                 | -           | -                      |
|   | Nasal congestion      | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|   | Oropharyngeal pain    | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Skin and subcutaneous tissue disorders          | Any PT                | 2                | -        | 2            | -          | 2                                 | -           | -                      |
|   | Dermatitis contact    | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|   | Rash maculo-papular   | 1                | -        | 1            | -          | 1                                 | -           | -                      |
| Vascular disorders                              | Systolic hypertension | 1                | 1        | -            | -          | 1                                 | -           | -                      |

**TABLE 4B(iv):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 56-70 years (N=30)**

| System Organ Class (SOC)                             | Preferred Term (PT)     | Total Events (n) | Severity |              |            | Relationship to Study Vaccination |             |                        |
|--|-------------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
|  |                         |                  | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| Any SOC  | Any PT                  | 32               | 17       | 13           | 2          | 28                                | 4           | -                      |
| Cardiac disorders                                    | Bradycardia             | 2                | 2        | -            | -          | 2                                 | -           | -                      |
| Ear and labyrinth disorders                          | Vertigo                 | 1                | 1        | -            | -          | -                                 | 1           | -                      |
| Gastrointestinal disorders                           | Any PT                  | 2                | 1        | 1            | -          | 1                                 | 1           | -                      |
|  | Abdominal discomfort    | 1                | -        | 1            | -          | -                                 | 1           | -                      |
|  | Haemorrhoids            | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| General disorders and administration site conditions | Injection site bruising | 2                | 2        | -            | -          | 2                                 | -           | -                      |
| Infections and infestations                          | Any PT                  | 4                | -        | 3            | 1          | 4                                 | -           | -                      |
|  | Onychomycosis           | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|  | Paronychia              | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|  | Urinary tract infection | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|  | Viral infection         | 1                | -        | -            | 1          | 1                                 | -           | -                      |
| Injury, poisoning and procedural complications       | Any PT                  | 6                | 3        | 3            | -          | 6                                 | -           | -                      |
|  | Arthropod sting         | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Exposure via inhalation | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|  | Limb injury             | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|  | Muscle strain           | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Skin laceration         | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Tooth fracture          | 1                | -        | 1            | -          | 1                                 | -           | -                      |

**TABLE 4B(iv):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 56-70 years (N=30) (continued)**

| System Organ Class (SOC)                        | Preferred Term (PT)    | Total Events (n) | Severity |              |            | Relationship to Study Vaccination |             |                        |
|---|------------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
|   |                        |                  | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| Investigations                                  | Bone density decreased | 1                | -        | 1            | -          | 1                                 | -           | -                      |
| Metabolism and nutrition disorders              | Any PT                 | 2                | -        | 1            | 1          | 1                                 | 1           | -                      |
|   | Decreased appetite     | 1                | -        | 1            | -          | -                                 | 1           | -                      |
|   | Hypoglycaemia          | 1                | -        | -            | 1          | 1                                 | -           | -                      |
| Musculoskeletal and connective tissue disorders | Pain in extremity      | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Nervous system disorders                        | Any PT                 | 4                | 3        | 1            | -          | 4                                 | -           | -                      |
|   | Dizziness              | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Headache               | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Sciatica               | 2                | 1        | 1            | -          | 2                                 | -           | -                      |
| Psychiatric disorders                           | Insomnia               | 1                | 1        | -            | -          | -                                 | 1           | -                      |
| Respiratory, thoracic and mediastinal disorders | Any PT                 | 3                | 2        | 1            | -          | 3                                 | -           | -                      |
|   | Nasal congestion       | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|   | Oropharyngeal pain     | 2                | 2        | -            | -          | 2                                 | -           | -                      |
| Skin and subcutaneous tissue disorders          | Any PT                 | 2                | -        | 2            | -          | 2                                 | -           | -                      |
|   | Dermatitis contact     | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|   | Rash maculo-papular    | 1                | -        | 1            | -          | 1                                 | -           | -                      |
| Vascular disorders                              | Systolic hypertension  | 1                | 1        | -            | -          | 1                                 | -           | -                      |

**TABLE 4C(i):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 25 mcg mRNA-1273 ≥71 years (N=10)**

| System Organ Class (SOC)                             | Preferred Term (PT)        | Total Events (n) | Severity |              |            | Relationship to Study Vaccination |             |                        |
|--|----------------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
|  |                            |                  | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| Any SOC  | Any PT                     | 28               | 26       | 2            | -          | 17                                | 11          | -                      |
| Cardiac disorders                                    | Bradycardia                | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| General disorders and administration site conditions | Any PT                     | 5                | 5        | -            | -          | 1                                 | 4           | -                      |
|  | Energy increased           | 2                | 2        | -            | -          | -                                 | 2           | -                      |
|  | Fatigue                    | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|  | Injection site bruising    | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Injection site pruritus    | 1                | 1        | -            | -          | -                                 | 1           | -                      |
| Infections and infestations                          | Pustule                    | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Injury, poisoning and procedural complications       | Any PT                     | 8                | 8        | -            | -          | 8                                 | -           | -                      |
|  | Arthropod bite             | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Limb injury                | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Procedural pain            | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Skin abrasion              | 3                | 3        | -            | -          | 3                                 | -           | -                      |
|  | Sunburn                    | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Thermal burn               | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Musculoskeletal and connective tissue disorders      | Any PT                     | 4                | 2        | 2            | -          | 4                                 | -           | -                      |
|  | Arthritis                  | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|  | Joint swelling             | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Muscle tightness           | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Musculoskeletal chest pain | 1                | -        | 1            | -          | 1                                 | -           | -                      |



**TABLE 4C(i):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 25 mcg mRNA-1273 ≥71 years (N=10) (continued)**

| System Organ Class (SOC)               | Preferred Term (PT) | Total Events (n) | Severity |              |            | Relationship to Study Vaccination |             |                        |
|--|---------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
|  |                     |                  | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| Nervous system disorders               | Any PT              | 3                | 3        | -            | -          | 1                                 | 2           | -                      |
|  | Dizziness           | 2                | 2        | -            | -          | 1                                 | 1           | -                      |
|  | Visual field defect | 1                | 1        | -            | -          | -                                 | 1           | -                      |
| Psychiatric disorders                  | Any PT              | 3                | 3        | -            | -          | -                                 | 3           | -                      |
|  | Anxiety             | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|  | Sleep disorder      | 2                | 2        | -            | -          | -                                 | 2           | -                      |
| Skin and subcutaneous tissue disorders | Any PT              | 3                | 3        | -            | -          | 1                                 | 2           | -                      |
|  | Night sweats        | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|  | Pruritus            | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|  | Skin irritation     | 1                | 1        | -            | -          | 1                                 | -           | -                      |

**TABLE 4C(ii):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 50 mcg mRNA-1273 ≥71 years (N=10)**

| System Organ Class (SOC)                             | Preferred Term (PT)     | Total Events (n) | Severity |              |            | Relationship to Study Vaccination |             |                        |
|--|-------------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
|  |                         |                  | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| Any SOC  | Any PT                  | 7                | 7        | -            | -          | 7                                 | -           | -                      |
| General disorders and administration site conditions | Injection site bruising | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Injury, poisoning and procedural complications       | Any PT                  | 3                | 3        | -            | -          | 3                                 | -           | -                      |
|  | Arthropod bite          | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Injury                  | 2                | 2        | -            | -          | 2                                 | -           | -                      |
| Respiratory, thoracic and mediastinal disorders      | Oropharyngeal pain      | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Vascular disorders                                   | Hypertension            | 2                | 2        | -            | -          | 2                                 | -           | -                      |

**TABLE 4C(iii):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 100 mcg mRNA-1273 ≥71 years (N=10)**

|   |                             |                  | Severity |              |            | Relationship to Study Vaccination |             |                        |
|---|-----------------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
| System Organ Class (SOC)  | Preferred Term (PT)         | Total Events (n) | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| Any SOC   | Any PT                      | 24               | 24       | -            | -          | 21                                | 3           | -                      |
| Cardiac disorders   | Bradycardia                 | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| General disorders and administration site conditions                | Any PT                      | 6                | 6        | -            | -          | 5                                 | 1           | -                      |
|   | Injection site bruising     | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Injection site erythema     | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|   | Vessel puncture site bruise | 4                | 4        | -            | -          | 4                                 | -           | -                      |
| Infections and infestations   | Urinary tract infection     | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Injury, poisoning and procedural complications                      | Any PT                      | 7                | 7        | -            | -          | 7                                 | -           | -                      |
|   | Contusion                   | 3                | 3        | -            | -          | 3                                 | -           | -                      |
|   | Skin abrasion               | 3                | 3        | -            | -          | 3                                 | -           | -                      |
|   | Tooth fracture              | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Musculoskeletal and connective tissue disorders                     | Myalgia                     | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Squamous cell carcinoma     | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Nervous system disorders  | Dizziness                   | 1                | 1        | -            | -          | -                                 | 1           | -                      |
| Skin and subcutaneous tissue disorders                              | Any PT                      | 5                | 5        | -            | -          | 4                                 | 1           | -                      |
|   | Blister                     | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Dermatitis                  | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Dermatitis contact          | 1                | 1        | -            | -          | 1                                 | -           | -                      |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4C(iii):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 100 mcg mRNA-1273 ≥71 years (N=10) (continued)**

|                          |                       |                  | Severity |              |            | Relationship to Study Vaccination |             |                        |
|--------------------------|-----------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
| System Organ Class (SOC) | Preferred Term (PT)   | Total Events (n) | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
|                          | Night sweats          | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|                          | Rash                  | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Vascular disorders       | Systolic hypertension | 1                | 1        | -            | -          | 1                                 | -           | -                      |

**TABLE 4C(iv):  
Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and  
Preferred Term, Severity, Relationship, and  
Vaccination Group – ≥71 years (N=30)**

|  |                             |                  | Severity |              |            | Relationship to Study Vaccination |             |                        |
|--|-----------------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
| System Organ Class (SOC)                             | Preferred Term (PT)         | Total Events (n) | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| Any SOC  | Any PT                      | 59               | 57       | 2            | -          | 45                                | 14          | -                      |
| Cardiac disorders                                    | Bradycardia                 | 2                | 2        | -            | -          | 2                                 | -           | -                      |
| General disorders and administration site conditions | Any PT                      | 12               | 12       | -            | -          | 7                                 | 5           | -                      |
|  | Energy increased            | 2                | 2        | -            | -          | -                                 | 2           | -                      |
|  | Fatigue                     | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|  | Injection site bruising     | 3                | 3        | -            | -          | 3                                 | -           | -                      |
|  | Injection site erythema     | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|  | Injection site pruritus     | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|  | Vessel puncture site bruise | 4                | 4        | -            | -          | 4                                 | -           | -                      |
| Infections and infestations                          | Any PT                      | 2                | 2        | -            | -          | 2                                 | -           | -                      |
|  | Pustule                     | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Urinary tract infection     | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Injury, poisoning and procedural complications       | Any PT                      | 18               | 18       | -            | -          | 18                                | -           | -                      |
|  | Arthropod bite              | 2                | 2        | -            | -          | 2                                 | -           | -                      |
|  | Contusion                   | 3                | 3        | -            | -          | 3                                 | -           | -                      |
|  | Injury                      | 2                | 2        | -            | -          | 2                                 | -           | -                      |
|  | Limb injury                 | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Procedural pain             | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|  | Skin abrasion               | 6                | 6        | -            | -          | 6                                 | -           | -                      |
|  | Sunburn                     | 1                | 1        | -            | -          | 1                                 | -           | -                      |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4C(iv):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – ≥71 years (N=30) (continued)**

|   |                            |                  | Severity |              |            | Relationship to Study Vaccination |             |                        |
|---|----------------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
| System Organ Class (SOC)  | Preferred Term (PT)        | Total Events (n) | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
| Musculoskeletal and connective tissue disorders                     | Thermal burn               | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Tooth fracture             | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Any PT                     | 5                | 3        | 2            | -          | 5                                 | -           | -                      |
|   | Arthritis                  | 1                | -        | 1            | -          | 1                                 | -           | -                      |
|   | Joint swelling             | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Muscle tightness           | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Musculoskeletal chest pain | 1                | -        | 1            | -          | 1                                 | -           | -                      |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Myalgia                    | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|   | Squamous cell carcinoma    | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Nervous system disorders  | Any PT                     | 4                | 4        | -            | -          | 1                                 | 3           | -                      |
|   | Dizziness                  | 3                | 3        | -            | -          | 1                                 | 2           | -                      |
|   | Visual field defect        | 1                | 1        | -            | -          | -                                 | 1           | -                      |
| Psychiatric disorders   | Any PT                     | 3                | 3        | -            | -          | -                                 | 3           | -                      |
|   | Anxiety                    | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|   | Sleep disorder             | 2                | 2        | -            | -          | -                                 | 2           | -                      |
| Respiratory, thoracic and mediastinal disorders                     | Oropharyngeal pain         | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Skin and subcutaneous tissue disorders                              | Any PT                     | 8                | 8        | -            | -          | 5                                 | 3           | -                      |
|   | Blister                    | 1                | 1        | -            | -          | 1                                 | -           | -                      |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4C(iv):**  
**Summary of All Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – ≥71 years (N=30) (continued)**

|                          |                       |                  | Severity |              |            | Relationship to Study Vaccination |             |                        |
|--------------------------|-----------------------|------------------|----------|--------------|------------|-----------------------------------|-------------|------------------------|
| System Organ Class (SOC) | Preferred Term (PT)   | Total Events (n) | Mild (n) | Moderate (n) | Severe (n) | Not Related (n)                   | Related (n) | Not Yet Determined (n) |
|                          | Dermatitis            | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|                          | Dermatitis contact    | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|                          | Night sweats          | 2                | 2        | -            | -          | -                                 | 2           | -                      |
|                          | Pruritus              | 1                | 1        | -            | -          | -                                 | 1           | -                      |
|                          | Rash                  | 1                | 1        | -            | -          | 1                                 | -           | -                      |
|                          | Skin irritation       | 1                | 1        | -            | -          | 1                                 | -           | -                      |
| Vascular disorders       | Any PT                | 3                | 3        | -            | -          | 3                                 | -           | -                      |
|                          | Hypertension          | 2                | 2        | -            | -          | 2                                 | -           | -                      |
|                          | Systolic hypertension | 1                | 1        | -            | -          | 1                                 | -           | -                      |

**TABLE 4D(i):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 25 mcg mRNA-1273 18-55 Years of Age (N=15)**

|  |                             |               |    | Severity |    |          |    |        |   | Relationship to Study Vaccination |    |         |    |
|--|-----------------------------|---------------|----|----------|----|----------|----|--------|---|-----------------------------------|----|---------|----|
|  |                             | Any Incidence |    | Mild     |    | Moderate |    | Severe |   | Not Related                       |    | Related |    |
| MedDRA System Organ Class                            | MedDRA Preferred Term       | n             | %  | n        | %  | n        | %  | n      | % | n                                 | %  | n       | %  |
| Any SOC  | Any PT                      | 12            | 80 | 12       | 80 | 3        | 20 | -      | - | 11                                | 73 | 4       | 27 |
| Gastrointestinal disorders                           | Any PT                      | 4             | 27 | 2        | 13 | 2        | 13 | -      | - | 3                                 | 20 | 1       | 7  |
|  | Flatulence                  | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
|  | Vomiting                    | 3             | 20 | 1        | 7  | 2        | 13 | -      | - | 2                                 | 13 | 1       | 7  |
| General disorders and administration site conditions | Any PT                      | 4             | 27 | 4        | 27 | -        | -  | -      | - | 4                                 | 27 | -       | -  |
|  | Fatigue                     | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
|  | Injection site irritation   | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
|  | Vessel puncture site bruise | 2             | 13 | 2        | 13 | -        | -  | -      | - | 2                                 | 13 | -       | -  |
| Infections and infestations                          | Any PT                      | 2             | 13 | 1        | 7  | 1        | 7  | -      | - | 2                                 | 13 | -       | -  |
|  | Hordeolum                   | 1             | 7  | -        | -  | 1        | 7  | -      | - | 1                                 | 7  | -       | -  |
|  | Pustule                     | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
| Injury, poisoning and procedural complications       | Any PT                      | 5             | 33 | 5        | 33 | -        | -  | -      | - | 5                                 | 33 | -       | -  |
|  | Contusion                   | 3             | 20 | 3        | 20 | -        | -  | -      | - | 3                                 | 20 | -       | -  |
|  | Muscle strain               | 2             | 13 | 2        | 13 | -        | -  | -      | - | 2                                 | 13 | -       | -  |
|  | Skin abrasion               | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
|  | Skin laceration             | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
|  | Wound                       | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
| Musculoskeletal and connective tissue disorders      | Any PT                      | 2             | 13 | 2        | 13 | -        | -  | -      | - | 1                                 | 7  | 1       | 7  |
|  | Muscular weakness           | 1             | 7  | 1        | 7  | -        | -  | -      | - | -                                 | -  | 1       | 7  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**TABLE 4D(i):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events by MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and Vaccination Group – 25 mcg mRNA-1273 18-55 Years of Age (N=15) (continued)**

|  |                       |               |    | Severity |    |          |   |        |   | Relationship to Study Vaccination |    |         |    |
|--|-----------------------|---------------|----|----------|----|----------|---|--------|---|-----------------------------------|----|---------|----|
|  |                       | Any Incidence |    | Mild     |    | Moderate |   | Severe |   | Not Related                       |    | Related |    |
| MedDRA System Organ Class  | MedDRA Preferred Term | n             | %  | n        | %  | n        | % | n      | % | n                                 | %  | n       | %  |
|  | Pain in jaw           | 1             | 7  | 1        | 7  | -        | - | -      | - | 1                                 | 7  | -       | -  |
| Nervous system disorders   | Presyncope            | 1             | 7  | 1        | 7  | -        | - | -      | - | 1                                 | 7  | -       | -  |
| Respiratory, thoracic and mediastinal disorders  | Any PT                | 2             | 13 | 2        | 13 | -        | - | -      | - | 2                                 | 13 | 1       | 7  |
|  | Dyspnoea exertional   | 1             | 7  | 1        | 7  | -        | - | -      | - | 1                                 | 7  | -       | -  |
|  | Oropharyngeal pain    | 1             | 7  | 1        | 7  | -        | - | -      | - | 1                                 | 7  | 1       | 7  |
| Skin and subcutaneous tissue disorders   | Any PT                | 4             | 27 | 4        | 27 | -        | - | -      | - | 2                                 | 13 | 2       | 13 |
|  | Dermatitis contact    | 1             | 7  | 1        | 7  | -        | - | -      | - | 1                                 | 7  | -       | -  |
|  | Erythema              | 1             | 7  | 1        | 7  | -        | - | -      | - | 1                                 | 7  | -       | -  |
|  | Petechiae             | 1             | 7  | 1        | 7  | -        | - | -      | - | -                                 | -  | 1       | 7  |
|  | Urticaria             | 1             | 7  | 1        | 7  | -        | - | -      | - | -                                 | -  | 1       | 7  |
| Vascular disorders   | Systolic hypertension | 1             | 7  | 1        | 7  | -        | - | -      | - | 1                                 | 7  | -       | -  |
| Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship. |                       |               |    |          |    |          |   |        |   |                                   |    |         |    |

**TABLE 4D(ii):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 50 mcg mRNA-1273 18-55 years (N=15)**

|  |                                      |               |    | Severity |    |          |    |        |   | Relationship to Study Vaccination |    |         |    |
|--|--------------------------------------|---------------|----|----------|----|----------|----|--------|---|-----------------------------------|----|---------|----|
|  |                                      | Any Incidence |    | Mild     |    | Moderate |    | Severe |   | Not Related                       |    | Related |    |
| MedDRA System Organ Class                            | MedDRA Preferred Term                | n             | %  | n        | %  | n        | %  | n      | % | n                                 | %  | n       | %  |
| Any SOC  | Any PT                               | 10            | 67 | 10       | 67 | 3        | 20 | -      | - | 8                                 | 53 | 6       | 40 |
| Blood and lymphatic system disorders                 | Lymphadenopathy                      | 1             | 7  | 1        | 7  | -        | -  | -      | - | -                                 | -  | 1       | 7  |
| Cardiac disorders                                    | Bradycardia                          | 2             | 13 | 2        | 13 | -        | -  | -      | - | 1                                 | 7  | 1       | 7  |
| Ear and labyrinth disorders                          | Vertigo                              | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
| Gastrointestinal disorders                           | Any PT                               | 3             | 20 | 1        | 7  | 2        | 13 | -      | - | 3                                 | 20 | 1       | 7  |
|  | Abdominal pain                       | 1             | 7  | -        | -  | 1        | 7  | -      | - | 1                                 | 7  | -       | -  |
|  | Diarrhoea                            | 1             | 7  | -        | -  | 1        | 7  | -      | - | -                                 | -  | 1       | 7  |
|  | Dyspepsia                            | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
|  | Tooth impacted                       | 1             | 7  | -        | -  | 1        | 7  | -      | - | 1                                 | 7  | -       | -  |
| General disorders and administration site conditions | Any PT                               | 3             | 20 | 3        | 20 | -        | -  | -      | - | 2                                 | 13 | 1       | 7  |
|  | Vaccination site movement impairment | 1             | 7  | 1        | 7  | -        | -  | -      | - | -                                 | -  | 1       | 7  |
|  | Vessel puncture site bruise          | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
|  | Vessel puncture site haemorrhage     | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
| Immune system disorders                              | Seasonal allergy                     | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
| Infections and infestations                          | Upper respiratory tract infection    | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |

**TABLE 4D(ii):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 50 mcg mRNA-1273 18-55 years (N=15) (continued)**

|   |                             |               |    | Severity |    |          |   |        |   | Relationship to Study Vaccination |    |         |   |
|---|-----------------------------|---------------|----|----------|----|----------|---|--------|---|-----------------------------------|----|---------|---|
|   |                             | Any Incidence |    | Mild     |    | Moderate |   | Severe |   | Not Related                       |    | Related |   |
| MedDRA System Organ Class                       | MedDRA Preferred Term       | n             | %  | n        | %  | n        | % | n      | % | n                                 | %  | n       | % |
| Injury, poisoning and procedural complications  | Skin abrasion               | 2             | 13 | 2        | 13 | -        | - | -      | - | 2                                 | 13 | -       | - |
| Investigations                                  | Blood glucose decreased     | 1             | 7  | 1        | 7  | -        | - | -      | - | 1                                 | 7  | -       | - |
| Musculoskeletal and connective tissue disorders | Any PT                      | 2             | 13 | 2        | 13 | -        | - | -      | - | 1                                 | 7  | 1       | 7 |
|   | Muscle spasms               | 1             | 7  | 1        | 7  | -        | - | -      | - | -                                 | -  | 1       | 7 |
|   | Myalgia                     | 1             | 7  | 1        | 7  | -        | - | -      | - | 1                                 | 7  | -       | - |
| Respiratory, thoracic and mediastinal disorders | Any PT                      | 2             | 13 | 2        | 13 | 1        | 7 | -      | - | 2                                 | 13 | 1       | 7 |
|   | Nasal congestion            | 1             | 7  | 1        | 7  | 1        | 7 | -      | - | 1                                 | 7  | 1       | 7 |
|   | Oropharyngeal pain          | 1             | 7  | 1        | 7  | -        | - | -      | - | 1                                 | 7  | -       | - |
|   | Upper-airway cough syndrome | 1             | 7  | 1        | 7  | -        | - | -      | - | 1                                 | 7  | 1       | 7 |
| Skin and subcutaneous tissue disorders          | Rash                        | 1             | 7  | 1        | 7  | -        | - | -      | - | 1                                 | 7  | -       | - |

Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship.

**TABLE 4D(iii):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 100 mcg mRNA-1273 18-55 years (N=15)**

|  |                         |               |    | Severity |    |          |    |        |   | Relationship to Study Vaccination |    |         |    |
|--|-------------------------|---------------|----|----------|----|----------|----|--------|---|-----------------------------------|----|---------|----|
|  |                         | Any Incidence |    | Mild     |    | Moderate |    | Severe |   | Not Related                       |    | Related |    |
| MedDRA System Organ Class                            | MedDRA Preferred Term   | n             | %  | n        | %  | n        | %  | n      | % | n                                 | %  | n       | %  |
| Any SOC  | Any PT                  | 11            | 73 | 9        | 60 | 5        | 33 | -      | - | 9                                 | 60 | 3       | 20 |
| Cardiac disorders                                    | Bradycardia             | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
| Eye disorders  | Eye irritation          | 1             | 7  | 1        | 7  | -        | -  | -      | - | -                                 | -  | 1       | 7  |
| Gastrointestinal disorders                           | Any PT                  | 2             | 13 | 1        | 7  | 1        | 7  | -      | - | 1                                 | 7  | 1       | 7  |
|  | Abdominal discomfort    | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
|  | Abdominal pain          | 1             | 7  | -        | -  | 1        | 7  | -      | - | -                                 | -  | 1       | 7  |
|  | Faeces discoloured      | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
| General disorders and administration site conditions | Any PT                  | 4             | 27 | 4        | 27 | 1        | 7  | -      | - | 3                                 | 20 | 2       | 13 |
|  | Feeling jittery         | 1             | 7  | -        | -  | 1        | 7  | -      | - | -                                 | -  | 1       | 7  |
|  | Injection site bruising | 3             | 20 | 3        | 20 | -        | -  | -      | - | 3                                 | 20 | -       | -  |
|  | Injection site pruritus | 2             | 13 | 2        | 13 | -        | -  | -      | - | -                                 | -  | 2       | 13 |
| Infections and infestations                          | Any PT                  | 2             | 13 | -        | -  | 2        | 13 | -      | - | 2                                 | 13 | -       | -  |
|  | Gastroenteritis         | 1             | 7  | -        | -  | 1        | 7  | -      | - | 1                                 | 7  | -       | -  |
|  | Infected cyst           | 1             | 7  | -        | -  | 1        | 7  | -      | - | 1                                 | 7  | -       | -  |
| Injury, poisoning and procedural complications       | Any PT                  | 3             | 20 | 2        | 13 | 1        | 7  | -      | - | 3                                 | 20 | -       | -  |
|  | Muscle strain           | 2             | 13 | 1        | 7  | 1        | 7  | -      | - | 2                                 | 13 | -       | -  |
|  | Thermal burn            | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
| Investigations                                       | Heart rate increased    | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |

**TABLE 4D(iii):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 100 mcg mRNA-1273 18-55 years (N=15) (continued)**

|  |  |               |    | Severity |    |          |   |        |   | Relationship to Study Vaccination |    |         |   |
|--|--|---------------|----|----------|----|----------|---|--------|---|-----------------------------------|----|---------|---|
|  |  | Any Incidence |    | Mild     |    | Moderate |   | Severe |   | Not Related                       |    | Related |   |
| MedDRA System Organ Class  | MedDRA Preferred Term                    | n             | %  | n        | %  | n        | % | n      | % | n                                 | %  | n       | % |
| Metabolism and nutrition disorders   | Decreased appetite                       | 1             | 7  | 1        | 7  | -        | - | -      | - | -                                 | -  | 1       | 7 |
| Musculoskeletal and connective tissue disorders  | Neck pain                                | 1             | 7  | 1        | 7  | -        | - | -      | - | 1                                 | 7  | -       | - |
| Nervous system disorders   | Dizziness                                | 1             | 7  | 1        | 7  | -        | - | -      | - | 1                                 | 7  | -       | - |
| Psychiatric disorders  | Attention deficit hyperactivity disorder | 1             | 7  | -        | -  | 1        | 7 | -      | - | 1                                 | 7  | -       | - |
| Reproductive system and breast disorders   | Breast pain                              | 1             | 7  | 1        | 7  | -        | - | -      | - | 1                                 | 7  | -       | - |
| Respiratory, thoracic and mediastinal disorders  | Any PT                                   | 3             | 20 | 3        | 20 | -        | - | -      | - | 2                                 | 13 | 1       | 7 |
|  | Diaphragmatic spasm                      | 1             | 7  | 1        | 7  | -        | - | -      | - | -                                 | -  | 1       | 7 |
|  | Nasal congestion                         | 1             | 7  | 1        | 7  | -        | - | -      | - | 1                                 | 7  | -       | - |
|  | Oropharyngeal pain                       | 1             | 7  | 1        | 7  | -        | - | -      | - | 1                                 | 7  | -       | - |
| Vascular disorders   | Vasodilatation                           | 1             | 7  | 1        | 7  | -        | - | -      | - | -                                 | -  | 1       | 7 |
| Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship. |  |               |    |          |    |          |   |        |   |                                   |    |         |   |

**TABLE 4D(iv):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 250 mcg mRNA-1273 18-55 years (N=15)**

|  |                             |               |    | Severity |    |          |    |        |   | Relationship to Study Vaccination |    |         |    |
|--|-----------------------------|---------------|----|----------|----|----------|----|--------|---|-----------------------------------|----|---------|----|
|  |                             | Any Incidence |    | Mild     |    | Moderate |    | Severe |   | Not Related                       |    | Related |    |
| MedDRA System Organ Class                            | MedDRA Preferred Term       | n             | %  | n        | %  | n        | %  | n      | % | n                                 | %  | n       | %  |
| Any SOC  | Any PT                      | 11            | 73 | 7        | 47 | 8        | 53 | 1      | 7 | 8                                 | 53 | 7       | 47 |
| Cardiac disorders                                    | Bradycardia                 | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
| Eye disorders  | Scintillating scotoma       | 1             | 7  | 1        | 7  | -        | -  | -      | - | -                                 | -  | 1       | 7  |
| Gastrointestinal disorders                           | Any PT                      | 6             | 40 | 5        | 33 | 1        | 7  | -      | - | 3                                 | 20 | 3       | 20 |
|  | Abdominal discomfort        | 1             | 7  | -        | -  | 1        | 7  | -      | - | -                                 | -  | 1       | 7  |
|  | Abdominal pain upper        | 1             | 7  | 1        | 7  | -        | -  | -      | - | -                                 | -  | 1       | 7  |
|  | Anal fissure                | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
|  | Dyspepsia                   | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
|  | Lip disorder                | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
|  | Vomiting                    | 1             | 7  | 1        | 7  | -        | -  | -      | - | -                                 | -  | 1       | 7  |
| General disorders and administration site conditions | Any PT                      | 3             | 20 | 2        | 13 | 2        | 13 | -      | - | 1                                 | 7  | 3       | 20 |
|  | Injection site erythema     | 2             | 13 | 1        | 7  | 1        | 7  | -      | - | -                                 | -  | 2       | 13 |
|  | Injection site pruritus     | 1             | 7  | 1        | 7  | -        | -  | -      | - | -                                 | -  | 1       | 7  |
|  | Malaise                     | 1             | 7  | -        | -  | 1        | 7  | -      | - | -                                 | -  | 1       | 7  |
|  | Vessel puncture site bruise | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
| Infections and infestations                          | Any PT                      | 2             | 13 | 1        | 7  | 1        | 7  | -      | - | 2                                 | 13 | -       | -  |
|  | Epididymitis                | 1             | 7  | -        | -  | 1        | 7  | -      | - | 1                                 | 7  | -       | -  |
|  | Urinary tract infection     | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4D(iv):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 250 mcg mRNA-1273 18-55 years (N=15) (continued)**

|   |                       |               |    | Severity |    |          |    |        |   | Relationship to Study Vaccination |    |         |    |
|---|-----------------------|---------------|----|----------|----|----------|----|--------|---|-----------------------------------|----|---------|----|
|   |                       | Any Incidence |    | Mild     |    | Moderate |    | Severe |   | Not Related                       |    | Related |    |
| MedDRA System Organ Class                       | MedDRA Preferred Term | n             | %  | n        | %  | n        | %  | n      | % | n                                 | %  | n       | %  |
| Metabolism and nutrition disorders              | Any PT                | 4             | 27 | 1        | 7  | 3        | 20 | -      | - | 1                                 | 7  | 3       | 20 |
|   | Decreased appetite    | 3             | 20 | 1        | 7  | 2        | 13 | -      | - | -                                 | -  | 3       | 20 |
|   | Hypoglycaemia         | 1             | 7  | -        | -  | 1        | 7  | -      | - | 1                                 | 7  | -       | -  |
| Musculoskeletal and connective tissue disorders | Any PT                | 4             | 27 | 2        | 13 | 2        | 13 | -      | - | 2                                 | 13 | 2       | 13 |
|   | Arthralgia            | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
|   | Muscle spasms         | 1             | 7  | -        | -  | 1        | 7  | -      | - | -                                 | -  | 1       | 7  |
|   | Muscle strain         | 1             | 7  | -        | -  | 1        | 7  | -      | - | 1                                 | 7  | -       | -  |
|   | Pain in extremity     | 1             | 7  | 1        | 7  | -        | -  | -      | - | -                                 | -  | 1       | 7  |
| Nervous system disorders                        | Any PT                | 3             | 20 | 1        | 7  | 1        | 7  | 1      | 7 | 2                                 | 13 | 1       | 7  |
|   | Dizziness             | 1             | 7  | -        | -  | -        | -  | 1      | 7 | -                                 | -  | 1       | 7  |
|   | Headache              | 2             | 13 | 1        | 7  | 1        | 7  | -      | - | 2                                 | 13 | -       | -  |
|   | Syncope               | 1             | 7  | -        | -  | -        | -  | 1      | 7 | -                                 | -  | 1       | 7  |
| Psychiatric disorders                           | Any PT                | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | 1       | 7  |
|   | Anxiety               | 1             | 7  | 1        | 7  | -        | -  | -      | - | -                                 | -  | 1       | 7  |
|   | Insomnia              | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
| Reproductive system and breast disorders        | Any PT                | 3             | 20 | 3        | 20 | -        | -  | -      | - | 2                                 | 13 | 1       | 7  |
|   | Vaginal haemorrhage   | 1             | 7  | 1        | 7  | -        | -  | -      | - | -                                 | -  | 1       | 7  |
|   | Vulvovaginal pruritus | 2             | 13 | 2        | 13 | -        | -  | -      | - | 2                                 | 13 | -       | -  |

**TABLE 4D(iv):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 250 mcg mRNA-1273 18-55 years (N=15) (continued)**

|  |                       |               |    | Severity |    |          |    |        |   | Relationship to Study Vaccination |    |         |    |
|--|-----------------------|---------------|----|----------|----|----------|----|--------|---|-----------------------------------|----|---------|----|
|  |                       | Any Incidence |    | Mild     |    | Moderate |    | Severe |   | Not Related                       |    | Related |    |
| MedDRA System Organ Class  | MedDRA Preferred Term | n             | %  | n        | %  | n        | %  | n      | % | n                                 | %  | n       | %  |
| Respiratory, thoracic and mediastinal disorders  | Oropharyngeal pain    | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
| Skin and subcutaneous tissue disorders   | Any PT                | 2             | 13 | -        | -  | 2        | 13 | -      | - | -                                 | -  | 2       | 13 |
|  | Hyperhidrosis         | 1             | 7  | -        | -  | 1        | 7  | -      | - | -                                 | -  | 1       | 7  |
|  | Night sweats          | 1             | 7  | -        | -  | 1        | 7  | -      | - | -                                 | -  | 1       | 7  |
| Vascular disorders   | Any PT                | 2             | 13 | 2        | 13 | -        | -  | -      | - | 2                                 | 13 | -       | -  |
|  | Hypertension          | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
|  | Hypotension           | 1             | 7  | 1        | 7  | -        | -  | -      | - | 1                                 | 7  | -       | -  |
| Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship. |                       |               |    |          |    |          |    |        |   |                                   |    |         |    |



**TABLE 4D(v):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 18-55 years (N=60)**

|                                      |                       |               |    | Severity |    |          |    |        |   | Relationship to Study Vaccination |    |         |    |
|--------------------------------------|-----------------------|---------------|----|----------|----|----------|----|--------|---|-----------------------------------|----|---------|----|
|                                      |                       | Any Incidence |    | Mild     |    | Moderate |    | Severe |   | Not Related                       |    | Related |    |
| MedDRA System Organ Class            | MedDRA Preferred Term | n             | %  | n        | %  | n        | %  | n      | % | n                                 | %  | n       | %  |
| Any SOC                              | Any PT                | 44            | 73 | 38       | 63 | 19       | 32 | 1      | 2 | 36                                | 60 | 20      | 33 |
| Blood and lymphatic system disorders | Lymphadenopathy       | 1             | 2  | 1        | 2  | -        | -  | -      | - | -                                 | -  | 1       | 2  |
| Cardiac disorders                    | Bradycardia           | 4             | 7  | 4        | 7  | -        | -  | -      | - | 3                                 | 5  | 1       | 2  |
| Ear and labyrinth disorders          | Vertigo               | 1             | 2  | 1        | 2  | -        | -  | -      | - | 1                                 | 2  | -       | -  |
| Eye disorders                        | Any PT                | 2             | 3  | 2        | 3  | -        | -  | -      | - | -                                 | -  | 2       | 3  |
|                                      | Eye irritation        | 1             | 2  | 1        | 2  | -        | -  | -      | - | -                                 | -  | 1       | 2  |
|                                      | Scintillating scotoma | 1             | 2  | 1        | 2  | -        | -  | -      | - | -                                 | -  | 1       | 2  |
| Gastrointestinal disorders           | Any PT                | 15            | 25 | 9        | 15 | 6        | 10 | -      | - | 10                                | 17 | 6       | 10 |
|                                      | Abdominal discomfort  | 2             | 3  | 1        | 2  | 1        | 2  | -      | - | 1                                 | 2  | 1       | 2  |
|                                      | Abdominal pain        | 2             | 3  | -        | -  | 2        | 3  | -      | - | 1                                 | 2  | 1       | 2  |
|                                      | Abdominal pain upper  | 1             | 2  | 1        | 2  | -        | -  | -      | - | -                                 | -  | 1       | 2  |
|                                      | Anal fissure          | 1             | 2  | 1        | 2  | -        | -  | -      | - | 1                                 | 2  | -       | -  |
|                                      | Diarrhoea             | 1             | 2  | -        | -  | 1        | 2  | -      | - | -                                 | -  | 1       | 2  |
|                                      | Dyspepsia             | 2             | 3  | 2        | 3  | -        | -  | -      | - | 2                                 | 3  | -       | -  |
|                                      | Faeces discoloured    | 1             | 2  | 1        | 2  | -        | -  | -      | - | 1                                 | 2  | -       | -  |
|                                      | Flatulence            | 1             | 2  | 1        | 2  | -        | -  | -      | - | 1                                 | 2  | -       | -  |
|                                      | Lip disorder          | 1             | 2  | 1        | 2  | -        | -  | -      | - | 1                                 | 2  | -       | -  |
|                                      | Tooth impacted        | 1             | 2  | -        | -  | 1        | 2  | -      | - | 1                                 | 2  | -       | -  |

**TABLE 4D(v):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 18-55 years (N=60) (continued)**

|  |                                      |               |    | Severity |    |          |   |        |   | Relationship to Study Vaccination |    |         |    |
|--|--------------------------------------|---------------|----|----------|----|----------|---|--------|---|-----------------------------------|----|---------|----|
|  |                                      | Any Incidence |    | Mild     |    | Moderate |   | Severe |   | Not Related                       |    | Related |    |
| MedDRA System Organ Class                            | MedDRA Preferred Term                | n             | %  | n        | %  | n        | % | n      | % | n                                 | %  | n       | %  |
|  | Vomiting                             | 4             | 7  | 2        | 3  | 2        | 3 | -      | - | 2                                 | 3  | 2       | 3  |
| General disorders and administration site conditions | Any PT                               | 14            | 23 | 13       | 22 | 3        | 5 | -      | - | 10                                | 17 | 6       | 10 |
|  | Fatigue                              | 1             | 2  | 1        | 2  | -        | - | -      | - | 1                                 | 2  | -       | -  |
|  | Feeling jittery                      | 1             | 2  | -        | -  | 1        | 2 | -      | - | -                                 | -  | 1       | 2  |
|  | Injection site bruising              | 3             | 5  | 3        | 5  | -        | - | -      | - | 3                                 | 5  | -       | -  |
|  | Injection site erythema              | 2             | 3  | 1        | 2  | 1        | 2 | -      | - | -                                 | -  | 2       | 3  |
|  | Injection site irritation            | 1             | 2  | 1        | 2  | -        | - | -      | - | 1                                 | 2  | -       | -  |
|  | Injection site pruritus              | 3             | 5  | 3        | 5  | -        | - | -      | - | -                                 | -  | 3       | 5  |
|  | Malaise                              | 1             | 2  | -        | -  | 1        | 2 | -      | - | -                                 | -  | 1       | 2  |
|  | Vaccination site movement impairment | 1             | 2  | 1        | 2  | -        | - | -      | - | -                                 | -  | 1       | 2  |
|  | Vessel puncture site bruise          | 4             | 7  | 4        | 7  | -        | - | -      | - | 4                                 | 7  | -       | -  |
|  | Vessel puncture site haemorrhage     | 1             | 2  | 1        | 2  | -        | - | -      | - | 1                                 | 2  | -       | -  |
| Immune system disorders                              | Seasonal allergy                     | 1             | 2  | 1        | 2  | -        | - | -      | - | 1                                 | 2  | -       | -  |
| Infections and infestations                          | Any PT                               | 7             | 12 | 3        | 5  | 4        | 7 | -      | - | 7                                 | 12 | -       | -  |
|  | Epididymitis                         | 1             | 2  | -        | -  | 1        | 2 | -      | - | 1                                 | 2  | -       | -  |
|  | Gastroenteritis                      | 1             | 2  | -        | -  | 1        | 2 | -      | - | 1                                 | 2  | -       | -  |
|  | Hordeolum                            | 1             | 2  | -        | -  | 1        | 2 | -      | - | 1                                 | 2  | -       | -  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4D(v):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 18-55 years (N=60) (continued)**

|  |                                   |               |    | Severity |    |          |   |        |   | Relationship to Study Vaccination |    |         |   |
|--|-----------------------------------|---------------|----|----------|----|----------|---|--------|---|-----------------------------------|----|---------|---|
|  |                                   | Any Incidence |    | Mild     |    | Moderate |   | Severe |   | Not Related                       |    | Related |   |
| MedDRA System Organ Class                      | MedDRA Preferred Term             | n             | %  | n        | %  | n        | % | n      | % | n                                 | %  | n       | % |
|  | Infected cyst                     | 1             | 2  | -        | -  | 1        | 2 | -      | - | 1                                 | 2  | -       | - |
|  | Pustule                           | 1             | 2  | 1        | 2  | -        | - | -      | - | 1                                 | 2  | -       | - |
|  | Upper respiratory tract infection | 1             | 2  | 1        | 2  | -        | - | -      | - | 1                                 | 2  | -       | - |
|  | Urinary tract infection           | 1             | 2  | 1        | 2  | -        | - | -      | - | 1                                 | 2  | -       | - |
| Injury, poisoning and procedural complications | Any PT                            | 10            | 17 | 9        | 15 | 1        | 2 | -      | - | 10                                | 17 | -       | - |
|  | Contusion                         | 3             | 5  | 3        | 5  | -        | - | -      | - | 3                                 | 5  | -       | - |
|  | Muscle strain                     | 4             | 7  | 3        | 5  | 1        | 2 | -      | - | 4                                 | 7  | -       | - |
|  | Skin abrasion                     | 3             | 5  | 3        | 5  | -        | - | -      | - | 3                                 | 5  | -       | - |
|  | Skin laceration                   | 1             | 2  | 1        | 2  | -        | - | -      | - | 1                                 | 2  | -       | - |
|  | Thermal burn                      | 1             | 2  | 1        | 2  | -        | - | -      | - | 1                                 | 2  | -       | - |
|  | Wound                             | 1             | 2  | 1        | 2  | -        | - | -      | - | 1                                 | 2  | -       | - |
| Investigations                                 | Any PT                            | 2             | 3  | 2        | 3  | -        | - | -      | - | 2                                 | 3  | -       | - |
|  | Blood glucose decreased           | 1             | 2  | 1        | 2  | -        | - | -      | - | 1                                 | 2  | -       | - |
|  | Heart rate increased              | 1             | 2  | 1        | 2  | -        | - | -      | - | 1                                 | 2  | -       | - |
| Metabolism and nutrition disorders             | Any PT                            | 5             | 8  | 2        | 3  | 3        | 5 | -      | - | 1                                 | 2  | 4       | 7 |
|  | Decreased appetite                | 4             | 7  | 2        | 3  | 2        | 3 | -      | - | -                                 | -  | 4       | 7 |
|  | Hypoglycaemia                     | 1             | 2  | -        | -  | 1        | 2 | -      | - | 1                                 | 2  | -       | - |
|  | Any PT                            | 9             | 15 | 7        | 12 | 2        | 3 | -      | - | 5                                 | 8  | 4       | 7 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4D(v):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 18-55 years (N=60) (continued)**

|   |  |               |   | Severity |   |          |   |        |   | Relationship to Study Vaccination |   |         |   |
|---|--|---------------|---|----------|---|----------|---|--------|---|-----------------------------------|---|---------|---|
|   |  | Any Incidence |   | Mild     |   | Moderate |   | Severe |   | Not Related                       |   | Related |   |
| MedDRA System Organ Class                       | MedDRA Preferred Term                    | n             | % | n        | % | n        | % | n      | % | n                                 | % | n       | % |
| Musculoskeletal and connective tissue disorders | Arthralgia                               | 1             | 2 | 1        | 2 | -        | - | -      | - | 1                                 | 2 | -       | - |
|   | Muscle spasms                            | 2             | 3 | 1        | 2 | 1        | 2 | -      | - | -                                 | - | 2       | 3 |
|   | Muscle strain                            | 1             | 2 | -        | - | 1        | 2 | -      | - | 1                                 | 2 | -       | - |
|   | Muscular weakness                        | 1             | 2 | 1        | 2 | -        | - | -      | - | -                                 | - | 1       | 2 |
|   | Myalgia                                  | 1             | 2 | 1        | 2 | -        | - | -      | - | 1                                 | 2 | -       | - |
|   | Neck pain                                | 1             | 2 | 1        | 2 | -        | - | -      | - | 1                                 | 2 | -       | - |
|   | Pain in extremity                        | 1             | 2 | 1        | 2 | -        | - | -      | - | -                                 | - | 1       | 2 |
|   | Pain in jaw                              | 1             | 2 | 1        | 2 | -        | - | -      | - | 1                                 | 2 | -       | - |
| Nervous system disorders                        | Any PT                                   | 5             | 8 | 3        | 5 | 1        | 2 | 1      | 2 | 4                                 | 7 | 1       | 2 |
|   | Dizziness                                | 2             | 3 | 1        | 2 | -        | - | 1      | 2 | 1                                 | 2 | 1       | 2 |
|   | Headache                                 | 2             | 3 | 1        | 2 | 1        | 2 | -      | - | 2                                 | 3 | -       | - |
|   | Presyncope                               | 1             | 2 | 1        | 2 | -        | - | -      | - | 1                                 | 2 | -       | - |
|   | Syncope                                  | 1             | 2 | -        | - | -        | - | 1      | 2 | -                                 | - | 1       | 2 |
| Psychiatric disorders                           | Any PT                                   | 2             | 3 | 1        | 2 | 1        | 2 | -      | - | 2                                 | 3 | 1       | 2 |
|   | Anxiety                                  | 1             | 2 | 1        | 2 | -        | - | -      | - | -                                 | - | 1       | 2 |
|   | Attention deficit hyperactivity disorder | 1             | 2 | -        | - | 1        | 2 | -      | - | 1                                 | 2 | -       | - |
|   | Insomnia                                 | 1             | 2 | 1        | 2 | -        | - | -      | - | 1                                 | 2 | -       | - |
|   | Any PT                                   | 4             | 7 | 4        | 7 | -        | - | -      | - | 3                                 | 5 | 1       | 2 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4D(v):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 18-55 years (N=60) (continued)**

|   |                             |               |    | Severity |    |          |   |        |   | Relationship to Study Vaccination |    |         |   |
|---|-----------------------------|---------------|----|----------|----|----------|---|--------|---|-----------------------------------|----|---------|---|
|   |                             | Any Incidence |    | Mild     |    | Moderate |   | Severe |   | Not Related                       |    | Related |   |
| MedDRA System Organ Class                       | MedDRA Preferred Term       | n             | %  | n        | %  | n        | % | n      | % | n                                 | %  | n       | % |
| Reproductive system and breast disorders        | Breast pain                 | 1             | 2  | 1        | 2  | -        | - | -      | - | 1                                 | 2  | -       | - |
|   | Vaginal haemorrhage         | 1             | 2  | 1        | 2  | -        | - | -      | - | -                                 | -  | 1       | 2 |
|   | Vulvovaginal pruritus       | 2             | 3  | 2        | 3  | -        | - | -      | - | 2                                 | 3  | -       | - |
| Respiratory, thoracic and mediastinal disorders | Any PT                      | 8             | 13 | 8        | 13 | 1        | 2 | -      | - | 7                                 | 12 | 3       | 5 |
|   | Diaphragmatic spasm         | 1             | 2  | 1        | 2  | -        | - | -      | - | -                                 | -  | 1       | 2 |
|   | Dyspnoea exertional         | 1             | 2  | 1        | 2  | -        | - | -      | - | 1                                 | 2  | -       | - |
|   | Nasal congestion            | 2             | 3  | 2        | 3  | 1        | 2 | -      | - | 2                                 | 3  | 1       | 2 |
|   | Oropharyngeal pain          | 4             | 7  | 4        | 7  | -        | - | -      | - | 4                                 | 7  | 1       | 2 |
|   | Upper-airway cough syndrome | 1             | 2  | 1        | 2  | -        | - | -      | - | 1                                 | 2  | 1       | 2 |
| Skin and subcutaneous tissue disorders          | Any PT                      | 7             | 12 | 5        | 8  | 2        | 3 | -      | - | 3                                 | 5  | 4       | 7 |
|   | Dermatitis contact          | 1             | 2  | 1        | 2  | -        | - | -      | - | 1                                 | 2  | -       | - |
|   | Erythema                    | 1             | 2  | 1        | 2  | -        | - | -      | - | 1                                 | 2  | -       | - |
|   | Hyperhidrosis               | 1             | 2  | -        | -  | 1        | 2 | -      | - | -                                 | -  | 1       | 2 |
|   | Night sweats                | 1             | 2  | -        | -  | 1        | 2 | -      | - | -                                 | -  | 1       | 2 |
|   | Petechiae                   | 1             | 2  | 1        | 2  | -        | - | -      | - | -                                 | -  | 1       | 2 |
|   | Rash                        | 1             | 2  | 1        | 2  | -        | - | -      | - | 1                                 | 2  | -       | - |
| Vascular disorders                              | Any PT                      | 4             | 7  | 4        | 7  | -        | - | -      | - | 3                                 | 5  | 1       | 2 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4D(v):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 18-55 years (N=60) (continued)**

|  |                       |               |   | Severity |   |          |   |        |   | Relationship to Study Vaccination |   |         |   |
|--|-----------------------|---------------|---|----------|---|----------|---|--------|---|-----------------------------------|---|---------|---|
|  |                       | Any Incidence |   | Mild     |   | Moderate |   | Severe |   | Not Related                       |   | Related |   |
| MedDRA System Organ Class  | MedDRA Preferred Term | n             | % | n        | % | n        | % | n      | % | n                                 | % | n       | % |
|  | Hypertension          | 1             | 2 | 1        | 2 | -        | - | -      | - | 1                                 | 2 | -       | - |
|  | Hypotension           | 1             | 2 | 1        | 2 | -        | - | -      | - | 1                                 | 2 | -       | - |
|  | Systolic hypertension | 1             | 2 | 1        | 2 | -        | - | -      | - | 1                                 | 2 | -       | - |
|  | Vasodilatation        | 1             | 2 | 1        | 2 | -        | - | -      | - | -                                 | - | 1       | 2 |
| Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship. |                       |               |   |          |   |          |   |        |   |                                   |   |         |   |

**TABLE 4E(i):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 25 mcg mRNA-1273 56-70 years (N=10)**

|  |                         |               |    | Severity |    |          |    |        |   | Relationship to Study Vaccination |    |         |    |
|--|-------------------------|---------------|----|----------|----|----------|----|--------|---|-----------------------------------|----|---------|----|
|  |                         | Any Incidence |    | Mild     |    | Moderate |    | Severe |   | Not Related                       |    | Related |    |
| MedDRA System Organ Class                            | MedDRA Preferred Term   | n             | %  | n        | %  | n        | %  | n      | % | n                                 | %  | n       | %  |
| Any SOC  | Any PT                  | 7             | 70 | 6        | 60 | 4        | 40 | -      | - | 5                                 | 50 | 2       | 20 |
| General disorders and administration site conditions | Injection site bruising | 2             | 20 | 2        | 20 | -        | -  | -      | - | 2                                 | 20 | -       | -  |
| Infections and infestations                          | Onychomycosis           | 1             | 10 | -        | -  | 1        | 10 | -      | - | 1                                 | 10 | -       | -  |
| Injury, poisoning and procedural complications       | Any PT                  | 2             | 20 | -        | -  | 2        | 20 | -      | - | 2                                 | 20 | -       | -  |
|  | Exposure via inhalation | 1             | 10 | -        | -  | 1        | 10 | -      | - | 1                                 | 10 | -       | -  |
|  | Limb injury             | 1             | 10 | -        | -  | 1        | 10 | -      | - | 1                                 | 10 | -       | -  |
| Investigations                                       | Bone density decreased  | 1             | 10 | -        | -  | 1        | 10 | -      | - | 1                                 | 10 | -       | -  |
| Metabolism and nutrition disorders                   | Decreased appetite      | 1             | 10 | -        | -  | 1        | 10 | -      | - | -                                 | -  | 1       | 10 |
| Musculoskeletal and connective tissue disorders      | Pain in extremity       | 1             | 10 | 1        | 10 | -        | -  | -      | - | 1                                 | 10 | -       | -  |
| Nervous system disorders                             | Any PT                  | 2             | 20 | 2        | 20 | 1        | 10 | -      | - | 2                                 | 20 | -       | -  |
|  | Headache                | 1             | 10 | 1        | 10 | -        | -  | -      | - | 1                                 | 10 | -       | -  |
|  | Sciatica                | 1             | 10 | 1        | 10 | 1        | 10 | -      | - | 1                                 | 10 | -       | -  |
| Psychiatric disorders                                | Insomnia                | 1             | 10 | 1        | 10 | -        | -  | -      | - | -                                 | -  | 1       | 10 |
| Respiratory, thoracic and mediastinal disorders      | Oropharyngeal pain      | 1             | 10 | 1        | 10 | -        | -  | -      | - | 1                                 | 10 | -       | -  |

Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship.

**TABLE 4E(ii):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 50 mcg mRNA-1273 56-70 years (N=10)**

|  |                         |               |    | Severity |    |          |    |        |    | Relationship to Study Vaccination |    |         |    |
|--|-------------------------|---------------|----|----------|----|----------|----|--------|----|-----------------------------------|----|---------|----|
|  |                         | Any Incidence |    | Mild     |    | Moderate |    | Severe |    | Not Related                       |    | Related |    |
| MedDRA System Organ Class                      | MedDRA Preferred Term   | n             | %  | n        | %  | n        | %  | n      | %  | n                                 | %  | n       | %  |
| Any SOC  | Any PT                  | 7             | 70 | 4        | 40 | 3        | 30 | 1      | 10 | 6                                 | 60 | 1       | 10 |
| Cardiac disorders                              | Bradycardia             | 2             | 20 | 2        | 20 | -        | -  | -      | -  | 2                                 | 20 | -       | -  |
| Gastrointestinal disorders                     | Abdominal discomfort    | 1             | 10 | -        | -  | 1        | 10 | -      | -  | -                                 | -  | 1       | 10 |
| Infections and infestations                    | Any PT                  | 2             | 20 | -        | -  | 1        | 10 | 1      | 10 | 2                                 | 20 | -       | -  |
|  | Urinary tract infection | 1             | 10 | -        | -  | 1        | 10 | -      | -  | 1                                 | 10 | -       | -  |
|  | Viral infection         | 1             | 10 | -        | -  | -        | -  | 1      | 10 | 1                                 | 10 | -       | -  |
| Injury, poisoning and procedural complications | Any PT                  | 3             | 30 | 2        | 20 | 1        | 10 | -      | -  | 3                                 | 30 | -       | -  |
|  | Muscle strain           | 1             | 10 | 1        | 10 | -        | -  | -      | -  | 1                                 | 10 | -       | -  |
|  | Skin laceration         | 1             | 10 | 1        | 10 | -        | -  | -      | -  | 1                                 | 10 | -       | -  |
|  | Tooth fracture          | 1             | 10 | -        | -  | 1        | 10 | -      | -  | 1                                 | 10 | -       | -  |

Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship.



**TABLE 4E(iii):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 100 mcg mRNA-1273 56-70 years (N=10)**

|  |                       |               |    | Severity |    |          |    |        |    | Relationship to Study Vaccination |    |         |    |
|--|-----------------------|---------------|----|----------|----|----------|----|--------|----|-----------------------------------|----|---------|----|
|  |                       | Any Incidence |    | Mild     |    | Moderate |    | Severe |    | Not Related                       |    | Related |    |
| MedDRA System Organ Class  | MedDRA Preferred Term | n             | %  | n        | %  | n        | %  | n      | %  | n                                 | %  | n       | %  |
| Any SOC  | Any PT                | 8             | 80 | 5        | 50 | 2        | 20 | 1      | 10 | 8                                 | 80 | 1       | 10 |
| Ear and labyrinth disorders  | Vertigo               | 1             | 10 | 1        | 10 | -        | -  | -      | -  | -                                 | -  | 1       | 10 |
| Gastrointestinal disorders   | Haemorrhoids          | 1             | 10 | 1        | 10 | -        | -  | -      | -  | 1                                 | 10 | -       | -  |
| Infections and infestations  | Paronychia            | 1             | 10 | -        | -  | 1        | 10 | -      | -  | 1                                 | 10 | -       | -  |
| Injury, poisoning and procedural complications   | Arthropod sting       | 1             | 10 | 1        | 10 | -        | -  | -      | -  | 1                                 | 10 | -       | -  |
| Metabolism and nutrition disorders   | Hypoglycaemia         | 1             | 10 | -        | -  | -        | -  | 1      | 10 | 1                                 | 10 | -       | -  |
| Nervous system disorders   | Dizziness             | 1             | 10 | 1        | 10 | -        | -  | -      | -  | 1                                 | 10 | -       | -  |
| Respiratory, thoracic and mediastinal disorders  | Any PT                | 2             | 20 | 1        | 10 | 1        | 10 | -      | -  | 2                                 | 20 | -       | -  |
|  | Nasal congestion      | 1             | 10 | -        | -  | 1        | 10 | -      | -  | 1                                 | 10 | -       | -  |
|  | Oropharyngeal pain    | 1             | 10 | 1        | 10 | -        | -  | -      | -  | 1                                 | 10 | -       | -  |
| Skin and subcutaneous tissue disorders   | Any PT                | 1             | 10 | -        | -  | 1        | 10 | -      | -  | 1                                 | 10 | -       | -  |
|  | Dermatitis contact    | 1             | 10 | -        | -  | 1        | 10 | -      | -  | 1                                 | 10 | -       | -  |
|  | Rash maculo-papular   | 1             | 10 | -        | -  | 1        | 10 | -      | -  | 1                                 | 10 | -       | -  |
| Vascular disorders   | Systolic hypertension | 1             | 10 | 1        | 10 | -        | -  | -      | -  | 1                                 | 10 | -       | -  |
| Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship. |                       |               |    |          |    |          |    |        |    |                                   |    |         |    |

**TABLE 4E(iv):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 56-70 years (N=30)**

|  |                         |               |    | Severity |    |          |    |        |   | Relationship to Study Vaccination |    |         |    |
|--|-------------------------|---------------|----|----------|----|----------|----|--------|---|-----------------------------------|----|---------|----|
|  |                         | Any Incidence |    | Mild     |    | Moderate |    | Severe |   | Not Related                       |    | Related |    |
| MedDRA System Organ Class                            | MedDRA Preferred Term   | n             | %  | n        | %  | n        | %  | n      | % | n                                 | %  | n       | %  |
| Any SOC  | Any PT                  | 22            | 73 | 15       | 50 | 9        | 30 | 2      | 7 | 19                                | 63 | 4       | 13 |
| Cardiac disorders                                    | Bradycardia             | 2             | 7  | 2        | 7  | -        | -  | -      | - | 2                                 | 7  | -       | -  |
| Ear and labyrinth disorders                          | Vertigo                 | 1             | 3  | 1        | 3  | -        | -  | -      | - | -                                 | -  | 1       | 3  |
| Gastrointestinal disorders                           | Any PT                  | 2             | 7  | 1        | 3  | 1        | 3  | -      | - | 1                                 | 3  | 1       | 3  |
|  | Abdominal discomfort    | 1             | 3  | -        | -  | 1        | 3  | -      | - | -                                 | -  | 1       | 3  |
|  | Haemorrhoids            | 1             | 3  | 1        | 3  | -        | -  | -      | - | 1                                 | 3  | -       | -  |
| General disorders and administration site conditions | Injection site bruising | 2             | 7  | 2        | 7  | -        | -  | -      | - | 2                                 | 7  | -       | -  |
| Infections and infestations                          | Any PT                  | 4             | 13 | -        | -  | 3        | 10 | 1      | 3 | 4                                 | 13 | -       | -  |
|  | Onychomycosis           | 1             | 3  | -        | -  | 1        | 3  | -      | - | 1                                 | 3  | -       | -  |
|  | Paronychia              | 1             | 3  | -        | -  | 1        | 3  | -      | - | 1                                 | 3  | -       | -  |
|  | Urinary tract infection | 1             | 3  | -        | -  | 1        | 3  | -      | - | 1                                 | 3  | -       | -  |
|  | Viral infection         | 1             | 3  | -        | -  | -        | -  | 1      | 3 | 1                                 | 3  | -       | -  |
| Injury, poisoning and procedural complications       | Any PT                  | 6             | 20 | 3        | 10 | 3        | 10 | -      | - | 6                                 | 20 | -       | -  |
|  | Arthropod sting         | 1             | 3  | 1        | 3  | -        | -  | -      | - | 1                                 | 3  | -       | -  |
|  | Exposure via inhalation | 1             | 3  | -        | -  | 1        | 3  | -      | - | 1                                 | 3  | -       | -  |
|  | Limb injury             | 1             | 3  | -        | -  | 1        | 3  | -      | - | 1                                 | 3  | -       | -  |
|  | Muscle strain           | 1             | 3  | 1        | 3  | -        | -  | -      | - | 1                                 | 3  | -       | -  |
|  | Skin laceration         | 1             | 3  | 1        | 3  | -        | -  | -      | - | 1                                 | 3  | -       | -  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4E(iv):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 56-70 years (N=30) (continued)**

|   |                        |               |    | Severity |    |          |   |        |   | Relationship to Study Vaccination |    |         |   |
|---|------------------------|---------------|----|----------|----|----------|---|--------|---|-----------------------------------|----|---------|---|
|   |                        | Any Incidence |    | Mild     |    | Moderate |   | Severe |   | Not Related                       |    | Related |   |
| MedDRA System Organ Class                       | MedDRA Preferred Term  | n             | %  | n        | %  | n        | % | n      | % | n                                 | %  | n       | % |
|   | Tooth fracture         | 1             | 3  | -        | -  | 1        | 3 | -      | - | 1                                 | 3  | -       | - |
| Investigations                                  | Bone density decreased | 1             | 3  | -        | -  | 1        | 3 | -      | - | 1                                 | 3  | -       | - |
| Metabolism and nutrition disorders              | Any PT                 | 2             | 7  | -        | -  | 1        | 3 | 1      | 3 | 1                                 | 3  | 1       | 3 |
|   | Decreased appetite     | 1             | 3  | -        | -  | 1        | 3 | -      | - | -                                 | -  | 1       | 3 |
|   | Hypoglycaemia          | 1             | 3  | -        | -  | -        | - | 1      | 3 | 1                                 | 3  | -       | - |
| Musculoskeletal and connective tissue disorders | Pain in extremity      | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | - |
| Nervous system disorders                        | Any PT                 | 3             | 10 | 3        | 10 | 1        | 3 | -      | - | 3                                 | 10 | -       | - |
|   | Dizziness              | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | - |
|   | Headache               | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | - |
|   | Sciatica               | 1             | 3  | 1        | 3  | 1        | 3 | -      | - | 1                                 | 3  | -       | - |
| Psychiatric disorders                           | Insomnia               | 1             | 3  | 1        | 3  | -        | - | -      | - | -                                 | -  | 1       | 3 |
| Respiratory, thoracic and mediastinal disorders | Any PT                 | 3             | 10 | 2        | 7  | 1        | 3 | -      | - | 3                                 | 10 | -       | - |
|   | Nasal congestion       | 1             | 3  | -        | -  | 1        | 3 | -      | - | 1                                 | 3  | -       | - |
|   | Oropharyngeal pain     | 2             | 7  | 2        | 7  | -        | - | -      | - | 2                                 | 7  | -       | - |
| Skin and subcutaneous tissue disorders          | Any PT                 | 1             | 3  | -        | -  | 1        | 3 | -      | - | 1                                 | 3  | -       | - |
|   | Dermatitis contact     | 1             | 3  | -        | -  | 1        | 3 | -      | - | 1                                 | 3  | -       | - |
|   | Rash maculo-papular    | 1             | 3  | -        | -  | 1        | 3 | -      | - | 1                                 | 3  | -       | - |
| Vascular disorders                              | Systolic hypertension  | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4E(iv):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 56-70 years (N=30) (continued)**

|  |                       |   |   |               | Severity |      |   |          |   |        | Relationship to Study Vaccination |             |   |         |   |
|--|-----------------------|---|---|---------------|----------|------|---|----------|---|--------|-----------------------------------|-------------|---|---------|---|
|  |                       |   |   | Any Incidence |          | Mild |   | Moderate |   | Severe |                                   | Not Related |   | Related |   |
| MedDRA System Organ Class  | MedDRA Preferred Term | n | % | n             | %        | n    | % | n        | % | n      | %                                 | n           | % | n       | % |
| Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship. |                       |   |   |               |          |      |   |          |   |        |                                   |             |   |         |   |

**TABLE 4F(i):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 25 mcg mRNA-1273 ≥71 years (N=10)**

|  |                         |               |    | Severity |    |          |    |        |   | Relationship to Study Vaccination |    |         |    |
|--|-------------------------|---------------|----|----------|----|----------|----|--------|---|-----------------------------------|----|---------|----|
|  |                         | Any Incidence |    | Mild     |    | Moderate |    | Severe |   | Not Related                       |    | Related |    |
| MedDRA System Organ Class                            | MedDRA Preferred Term   | n             | %  | n        | %  | n        | %  | n      | % | n                                 | %  | n       | %  |
| Any SOC  | Any PT                  | 9             | 90 | 9        | 90 | 2        | 20 | -      | - | 7                                 | 70 | 4       | 40 |
| Cardiac disorders                                    | Bradycardia             | 1             | 10 | 1        | 10 | -        | -  | -      | - | 1                                 | 10 | -       | -  |
| General disorders and administration site conditions | Any PT                  | 2             | 20 | 2        | 20 | -        | -  | -      | - | 1                                 | 10 | 1       | 10 |
|  | Energy increased        | 1             | 10 | 1        | 10 | -        | -  | -      | - | -                                 | -  | 1       | 10 |
|  | Fatigue                 | 1             | 10 | 1        | 10 | -        | -  | -      | - | -                                 | -  | 1       | 10 |
|  | Injection site bruising | 1             | 10 | 1        | 10 | -        | -  | -      | - | 1                                 | 10 | -       | -  |
|  | Injection site pruritus | 1             | 10 | 1        | 10 | -        | -  | -      | - | -                                 | -  | 1       | 10 |
| Infections and infestations                          | Pustule                 | 1             | 10 | 1        | 10 | -        | -  | -      | - | 1                                 | 10 | -       | -  |
| Injury, poisoning and procedural complications       | Any PT                  | 5             | 50 | 5        | 50 | -        | -  | -      | - | 5                                 | 50 | -       | -  |
|  | Arthropod bite          | 1             | 10 | 1        | 10 | -        | -  | -      | - | 1                                 | 10 | -       | -  |
|  | Limb injury             | 1             | 10 | 1        | 10 | -        | -  | -      | - | 1                                 | 10 | -       | -  |
|  | Procedural pain         | 1             | 10 | 1        | 10 | -        | -  | -      | - | 1                                 | 10 | -       | -  |
|  | Skin abrasion           | 3             | 30 | 3        | 30 | -        | -  | -      | - | 3                                 | 30 | -       | -  |
|  | Sunburn                 | 1             | 10 | 1        | 10 | -        | -  | -      | - | 1                                 | 10 | -       | -  |
|  | Thermal burn            | 1             | 10 | 1        | 10 | -        | -  | -      | - | 1                                 | 10 | -       | -  |
| Musculoskeletal and connective tissue disorders      | Any PT                  | 4             | 40 | 2        | 20 | 2        | 20 | -      | - | 4                                 | 40 | -       | -  |
|  | Arthritis               | 1             | 10 | -        | -  | 1        | 10 | -      | - | 1                                 | 10 | -       | -  |
|  | Joint swelling          | 1             | 10 | 1        | 10 | -        | -  | -      | - | 1                                 | 10 | -       | -  |
|  | Muscle tightness        | 1             | 10 | 1        | 10 | -        | -  | -      | - | 1                                 | 10 | -       | -  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4F(i):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 25 mcg mRNA-1273 ≥71 years (N=10)**

|  |                            |               |    | Severity |    |          |    |        |   | Relationship to Study Vaccination |    |         |    |
|--|----------------------------|---------------|----|----------|----|----------|----|--------|---|-----------------------------------|----|---------|----|
|  |                            | Any Incidence |    | Mild     |    | Moderate |    | Severe |   | Not Related                       |    | Related |    |
| MedDRA System Organ Class              | MedDRA Preferred Term      | n             | %  | n        | %  | n        | %  | n      | % | n                                 | %  | n       | %  |
|  | Musculoskeletal chest pain | 1             | 10 | -        | -  | 1        | 10 | -      | - | 1                                 | 10 | -       | -  |
| Nervous system disorders               | Any PT                     | 2             | 20 | 2        | 20 | -        | -  | -      | - | 1                                 | 10 | 2       | 20 |
|  | Dizziness                  | 2             | 20 | 2        | 20 | -        | -  | -      | - | 1                                 | 10 | 1       | 10 |
|  | Visual field defect        | 1             | 10 | 1        | 10 | -        | -  | -      | - | -                                 | -  | 1       | 10 |
| Psychiatric disorders                  | Any PT                     | 2             | 20 | 2        | 20 | -        | -  | -      | - | -                                 | -  | 2       | 20 |
|  | Anxiety                    | 1             | 10 | 1        | 10 | -        | -  | -      | - | -                                 | -  | 1       | 10 |
|  | Sleep disorder             | 1             | 10 | 1        | 10 | -        | -  | -      | - | -                                 | -  | 1       | 10 |
| Skin and subcutaneous tissue disorders | Any PT                     | 3             | 30 | 3        | 30 | -        | -  | -      | - | 1                                 | 10 | 2       | 20 |
|  | Night sweats               | 1             | 10 | 1        | 10 | -        | -  | -      | - | -                                 | -  | 1       | 10 |
|  | Pruritus                   | 1             | 10 | 1        | 10 | -        | -  | -      | - | -                                 | -  | 1       | 10 |
|  | Skin irritation            | 1             | 10 | 1        | 10 | -        | -  | -      | - | 1                                 | 10 | -       | -  |

Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship.

**TABLE 4F(ii):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 50 mcg mRNA-1273 ≥71 years (N=10)**

|  |                         |               |    | Severity |    |          |   |        |   | Relationship to Study Vaccination |    |         |   |
|--|-------------------------|---------------|----|----------|----|----------|---|--------|---|-----------------------------------|----|---------|---|
|  |                         | Any Incidence |    | Mild     |    | Moderate |   | Severe |   | Not Related                       |    | Related |   |
| MedDRA System Organ Class  | MedDRA Preferred Term   | n             | %  | n        | %  | n        | % | n      | % | n                                 | %  | n       | % |
| Any SOC  | Any PT                  | 6             | 60 | 6        | 60 | -        | - | -      | - | 6                                 | 60 | -       | - |
| General disorders and administration site conditions   | Injection site bruising | 1             | 10 | 1        | 10 | -        | - | -      | - | 1                                 | 10 | -       | - |
| Injury, poisoning and procedural complications   | Any PT                  | 2             | 20 | 2        | 20 | -        | - | -      | - | 2                                 | 20 | -       | - |
|  | Arthropod bite          | 1             | 10 | 1        | 10 | -        | - | -      | - | 1                                 | 10 | -       | - |
|  | Injury                  | 2             | 20 | 2        | 20 | -        | - | -      | - | 2                                 | 20 | -       | - |
| Respiratory, thoracic and mediastinal disorders  | Oropharyngeal pain      | 1             | 10 | 1        | 10 | -        | - | -      | - | 1                                 | 10 | -       | - |
| Vascular disorders   | Hypertension            | 2             | 20 | 2        | 20 | -        | - | -      | - | 2                                 | 20 | -       | - |
| Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship. |                         |               |    |          |    |          |   |        |   |                                   |    |         |   |

**TABLE 4F(iii):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 100 mcg mRNA-1273 ≥71 years (N=10)**

|   |                             |               |    | Severity |    |          |   |        |   | Relationship to Study Vaccination |    |         |    |
|---|-----------------------------|---------------|----|----------|----|----------|---|--------|---|-----------------------------------|----|---------|----|
|   |                             | Any Incidence |    | Mild     |    | Moderate |   | Severe |   | Not Related                       |    | Related |    |
| MedDRA System Organ Class   | MedDRA Preferred Term       | n             | %  | n        | %  | n        | % | n      | % | n                                 | %  | n       | %  |
| Any SOC   | Any PT                      | 8             | 80 | 8        | 80 | -        | - | -      | - | 7                                 | 70 | 3       | 30 |
| Cardiac disorders   | Bradycardia                 | 1             | 10 | 1        | 10 | -        | - | -      | - | 1                                 | 10 | -       | -  |
| General disorders and administration site conditions                | Any PT                      | 4             | 40 | 4        | 40 | -        | - | -      | - | 3                                 | 30 | 1       | 10 |
|   | Injection site bruising     | 1             | 10 | 1        | 10 | -        | - | -      | - | 1                                 | 10 | -       | -  |
|   | Injection site erythema     | 1             | 10 | 1        | 10 | -        | - | -      | - | -                                 | -  | 1       | 10 |
|   | Vessel puncture site bruise | 3             | 30 | 3        | 30 | -        | - | -      | - | 3                                 | 30 | -       | -  |
| Infections and infestations   | Urinary tract infection     | 1             | 10 | 1        | 10 | -        | - | -      | - | 1                                 | 10 | -       | -  |
| Injury, poisoning and procedural complications                      | Any PT                      | 4             | 40 | 4        | 40 | -        | - | -      | - | 4                                 | 40 | -       | -  |
|   | Contusion                   | 2             | 20 | 2        | 20 | -        | - | -      | - | 2                                 | 20 | -       | -  |
|   | Skin abrasion               | 3             | 30 | 3        | 30 | -        | - | -      | - | 3                                 | 30 | -       | -  |
|   | Tooth fracture              | 1             | 10 | 1        | 10 | -        | - | -      | - | 1                                 | 10 | -       | -  |
| Musculoskeletal and connective tissue disorders                     | Myalgia                     | 1             | 10 | 1        | 10 | -        | - | -      | - | 1                                 | 10 | -       | -  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Squamous cell carcinoma     | 1             | 10 | 1        | 10 | -        | - | -      | - | 1                                 | 10 | -       | -  |
| Nervous system disorders  | Dizziness                   | 1             | 10 | 1        | 10 | -        | - | -      | - | -                                 | -  | 1       | 10 |
| Skin and subcutaneous tissue disorders                              | Any PT                      | 4             | 40 | 4        | 40 | -        | - | -      | - | 3                                 | 30 | 1       | 10 |
|   | Blister                     | 1             | 10 | 1        | 10 | -        | - | -      | - | 1                                 | 10 | -       | -  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**TABLE 4F(iii):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – 100 mcg mRNA-1273 ≥71 years (N=10) (continued)**

|                           |                       |               |    | Severity |    |          |   |        |   | Relationship to Study Vaccination |    |         |    |
|---------------------------|-----------------------|---------------|----|----------|----|----------|---|--------|---|-----------------------------------|----|---------|----|
|                           |                       | Any Incidence |    | Mild     |    | Moderate |   | Severe |   | Not Related                       |    | Related |    |
| MedDRA System Organ Class | MedDRA Preferred Term | n             | %  | n        | %  | n        | % | n      | % | n                                 | %  | n       | %  |
|                           | Dermatitis            | 1             | 10 | 1        | 10 | -        | - | -      | - | 1                                 | 10 | -       | -  |
|                           | Dermatitis contact    | 1             | 10 | 1        | 10 | -        | - | -      | - | 1                                 | 10 | -       | -  |
|                           | Night sweats          | 1             | 10 | 1        | 10 | -        | - | -      | - | -                                 | -  | 1       | 10 |
|                           | Rash                  | 1             | 10 | 1        | 10 | -        | - | -      | - | 1                                 | 10 | -       | -  |
| Vascular disorders        | Systolic hypertension | 1             | 10 | 1        | 10 | -        | - | -      | - | 1                                 | 10 | -       | -  |

Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship.

**TABLE 4F(iv):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – ≥71 years (N=30)**

|  |                             |               |    | Severity |    |          |   |        |   | Relationship to Study Vaccination |    |         |    |
|--|-----------------------------|---------------|----|----------|----|----------|---|--------|---|-----------------------------------|----|---------|----|
|  |                             | Any Incidence |    | Mild     |    | Moderate |   | Severe |   | Not Related                       |    | Related |    |
| MedDRA System Organ Class                            | MedDRA Preferred Term       | n             | %  | n        | %  | n        | % | n      | % | n                                 | %  | n       | %  |
| Any SOC  | Any PT                      | 23            | 77 | 23       | 77 | 2        | 7 | -      | - | 20                                | 67 | 7       | 23 |
| Cardiac disorders                                    | Bradycardia                 | 2             | 7  | 2        | 7  | -        | - | -      | - | 2                                 | 7  | -       | -  |
| General disorders and administration site conditions | Any PT                      | 7             | 23 | 7        | 23 | -        | - | -      | - | 5                                 | 17 | 2       | 7  |
|  | Energy increased            | 1             | 3  | 1        | 3  | -        | - | -      | - | -                                 | -  | 1       | 3  |
|  | Fatigue                     | 1             | 3  | 1        | 3  | -        | - | -      | - | -                                 | -  | 1       | 3  |
|  | Injection site bruising     | 3             | 10 | 3        | 10 | -        | - | -      | - | 3                                 | 10 | -       | -  |
|  | Injection site erythema     | 1             | 3  | 1        | 3  | -        | - | -      | - | -                                 | -  | 1       | 3  |
|  | Injection site pruritus     | 1             | 3  | 1        | 3  | -        | - | -      | - | -                                 | -  | 1       | 3  |
|  | Vessel puncture site bruise | 3             | 10 | 3        | 10 | -        | - | -      | - | 3                                 | 10 | -       | -  |
| Infections and infestations                          | Any PT                      | 2             | 7  | 2        | 7  | -        | - | -      | - | 2                                 | 7  | -       | -  |
|  | Pustule                     | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | -  |
|  | Urinary tract infection     | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | -  |
| Injury, poisoning and procedural complications       | Any PT                      | 11            | 37 | 11       | 37 | -        | - | -      | - | 11                                | 37 | -       | -  |
|  | Arthropod bite              | 2             | 7  | 2        | 7  | -        | - | -      | - | 2                                 | 7  | -       | -  |
|  | Contusion                   | 2             | 7  | 2        | 7  | -        | - | -      | - | 2                                 | 7  | -       | -  |
|  | Injury                      | 2             | 7  | 2        | 7  | -        | - | -      | - | 2                                 | 7  | -       | -  |
|  | Limb injury                 | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | -  |
|  | Procedural pain             | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | -  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4F(iv):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – ≥71 years (N=30) (continued)**

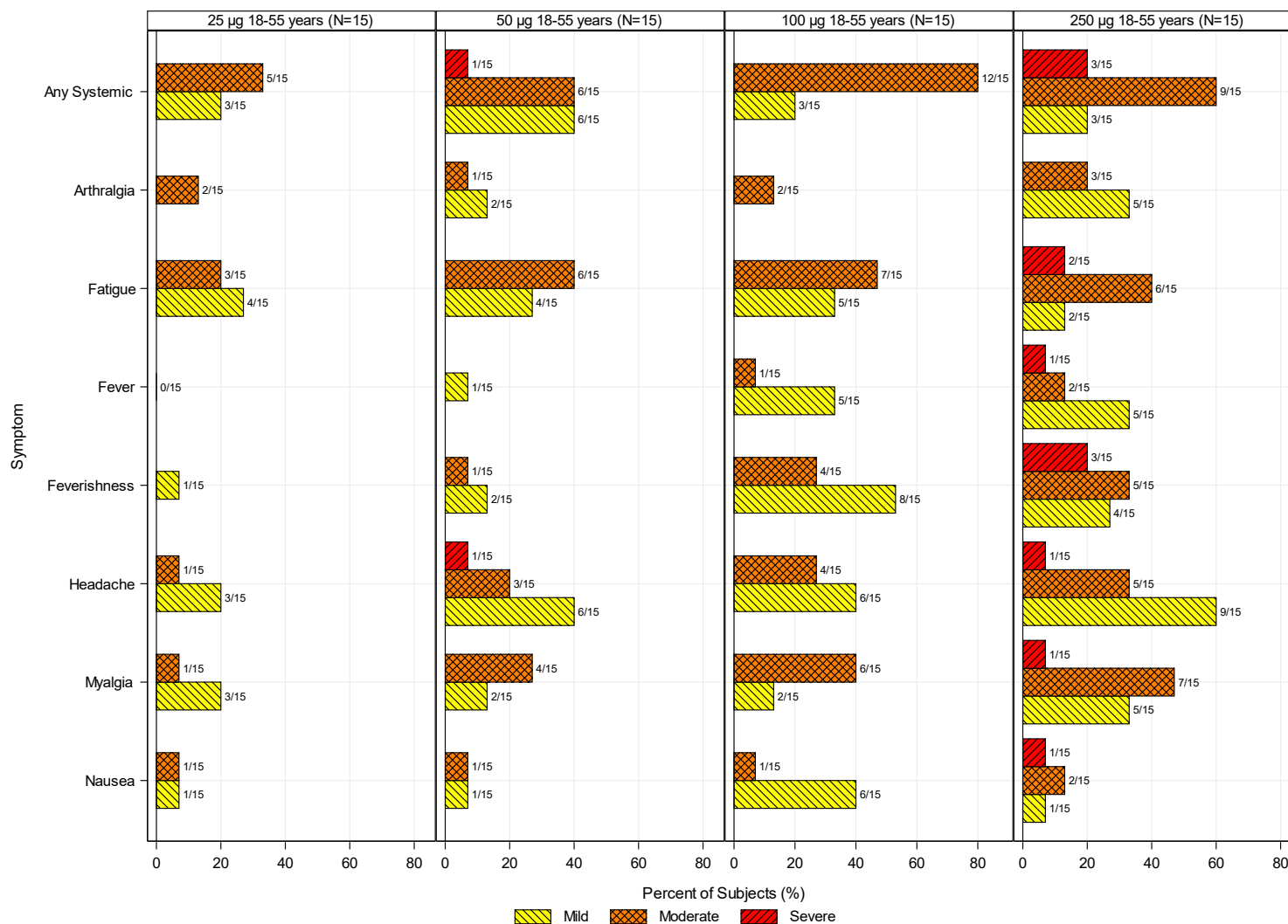
|   |                            |               |    | Severity |    |          |   |        |   | Relationship to Study Vaccination |    |         |    |
|---|----------------------------|---------------|----|----------|----|----------|---|--------|---|-----------------------------------|----|---------|----|
|   |                            | Any Incidence |    | Mild     |    | Moderate |   | Severe |   | Not Related                       |    | Related |    |
| MedDRA System Organ Class   | MedDRA Preferred Term      | n             | %  | n        | %  | n        | % | n      | % | n                                 | %  | n       | %  |
|   | Skin abrasion              | 6             | 20 | 6        | 20 | -        | - | -      | - | 6                                 | 20 | -       | -  |
|   | Sunburn                    | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | -  |
|   | Thermal burn               | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | -  |
|   | Tooth fracture             | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | -  |
| Musculoskeletal and connective tissue disorders                     | Any PT                     | 5             | 17 | 3        | 10 | 2        | 7 | -      | - | 5                                 | 17 | -       | -  |
|   | Arthritis                  | 1             | 3  | -        | -  | 1        | 3 | -      | - | 1                                 | 3  | -       | -  |
|   | Joint swelling             | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | -  |
|   | Muscle tightness           | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | -  |
|   | Musculoskeletal chest pain | 1             | 3  | -        | -  | 1        | 3 | -      | - | 1                                 | 3  | -       | -  |
|   | Myalgia                    | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | -  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Squamous cell carcinoma    | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | -  |
| Nervous system disorders  | Any PT                     | 3             | 10 | 3        | 10 | -        | - | -      | - | 1                                 | 3  | 3       | 10 |
|   | Dizziness                  | 3             | 10 | 3        | 10 | -        | - | -      | - | 1                                 | 3  | 2       | 7  |
|   | Visual field defect        | 1             | 3  | 1        | 3  | -        | - | -      | - | -                                 | -  | 1       | 3  |
| Psychiatric disorders   | Any PT                     | 2             | 7  | 2        | 7  | -        | - | -      | - | -                                 | -  | 2       | 7  |
|   | Anxiety                    | 1             | 3  | 1        | 3  | -        | - | -      | - | -                                 | -  | 1       | 3  |
|   | Sleep disorder             | 1             | 3  | 1        | 3  | -        | - | -      | - | -                                 | -  | 1       | 3  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 4F(iv):**  
**Number and Percentage of Subjects Experiencing Unsolicited Adverse Events**  
**MedDRA® System Organ Class and Preferred Term, Severity, Relationship, and**  
**Vaccination Group – ≥71 years (N=30) (continued)**

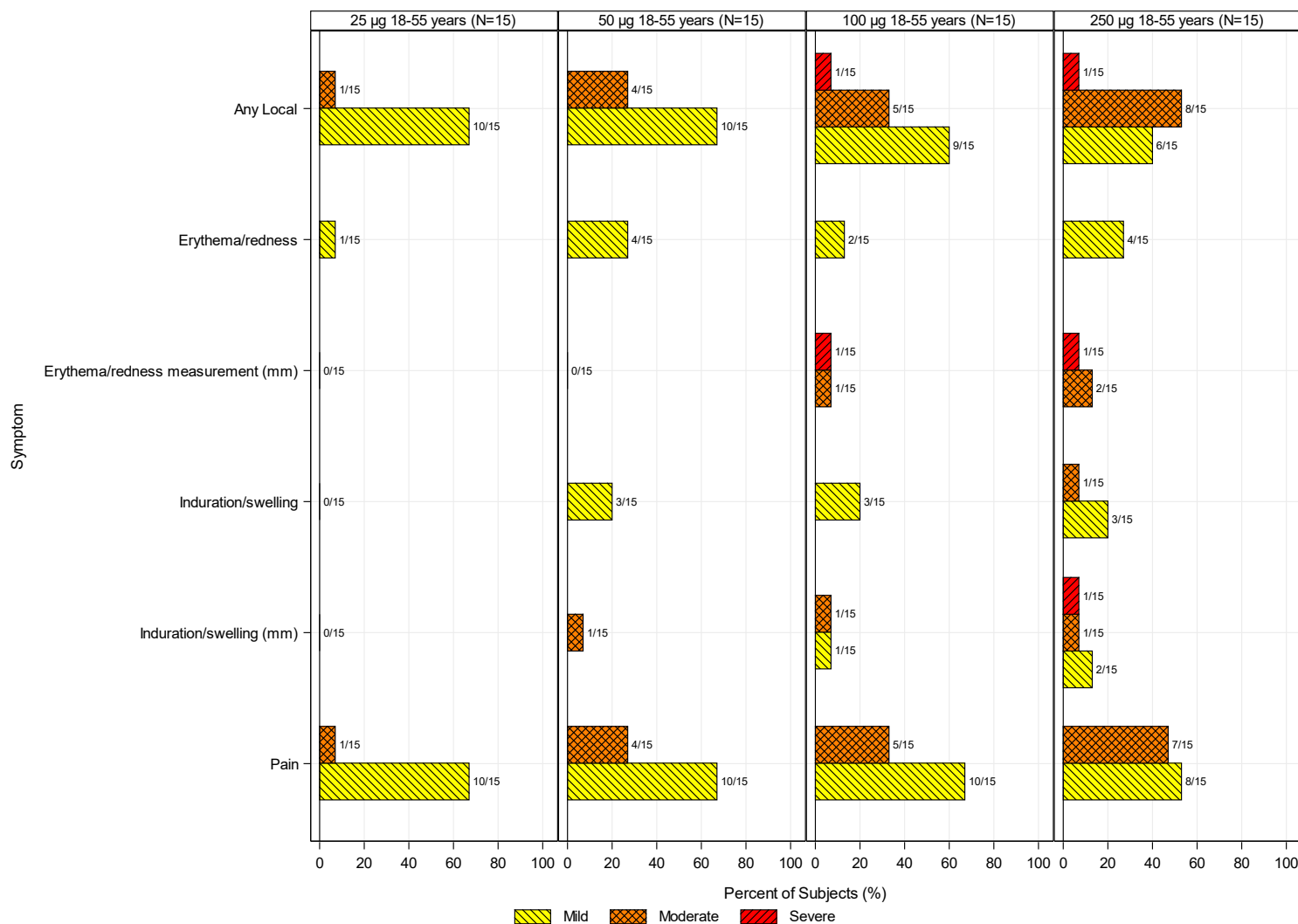
|  |                       |               |    | Severity |    |          |   |        |   | Relationship to Study Vaccination |    |         |    |
|--|-----------------------|---------------|----|----------|----|----------|---|--------|---|-----------------------------------|----|---------|----|
|  |                       | Any Incidence |    | Mild     |    | Moderate |   | Severe |   | Not Related                       |    | Related |    |
| MedDRA System Organ Class  | MedDRA Preferred Term | n             | %  | n        | %  | n        | % | n      | % | n                                 | %  | n       | %  |
| Respiratory, thoracic and mediastinal disorders  | Oropharyngeal pain    | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | -  |
| Skin and subcutaneous tissue disorders   | Any PT                | 7             | 23 | 7        | 23 | -        | - | -      | - | 4                                 | 13 | 3       | 10 |
|  | Blister               | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | -  |
|  | Dermatitis            | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | -  |
|  | Dermatitis contact    | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | -  |
|  | Night sweats          | 2             | 7  | 2        | 7  | -        | - | -      | - | -                                 | -  | 2       | 7  |
|  | Pruritus              | 1             | 3  | 1        | 3  | -        | - | -      | - | -                                 | -  | 1       | 3  |
|  | Rash                  | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | -  |
|  | Skin irritation       | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | -  |
| Vascular disorders   | Any PT                | 3             | 10 | 3        | 10 | -        | - | -      | - | 3                                 | 10 | -       | -  |
|  | Hypertension          | 2             | 7  | 2        | 7  | -        | - | -      | - | 2                                 | 7  | -       | -  |
|  | Systolic hypertension | 1             | 3  | 1        | 3  | -        | - | -      | - | 1                                 | 3  | -       | -  |
| Note: This table presents number and percentage of subjects. A subject is only counted once per PT and is summarized according to their highest severity and closest relationship. |                       |               |    |          |    |          |   |        |   |                                   |    |         |    |

**FIGURE 1A(i):  
Maximum Severity of Solicited Events by Symptom and Vaccination Group - Systemic - 18-55 Years of Age**



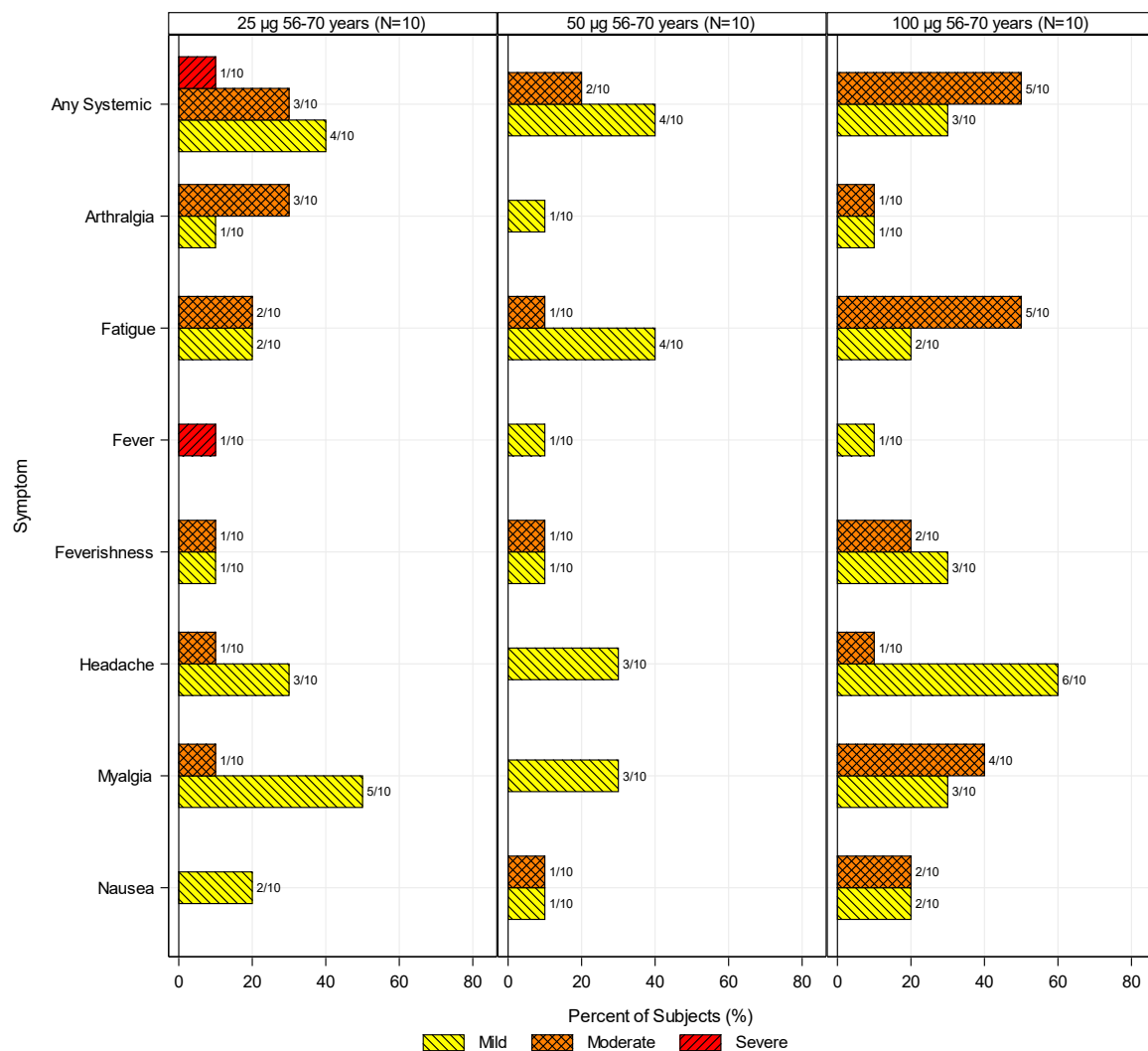
Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 1A(ii):  
Maximum Severity of Solicited Events by Symptom and Vaccination Group – Local - 18-55 Years of Age**



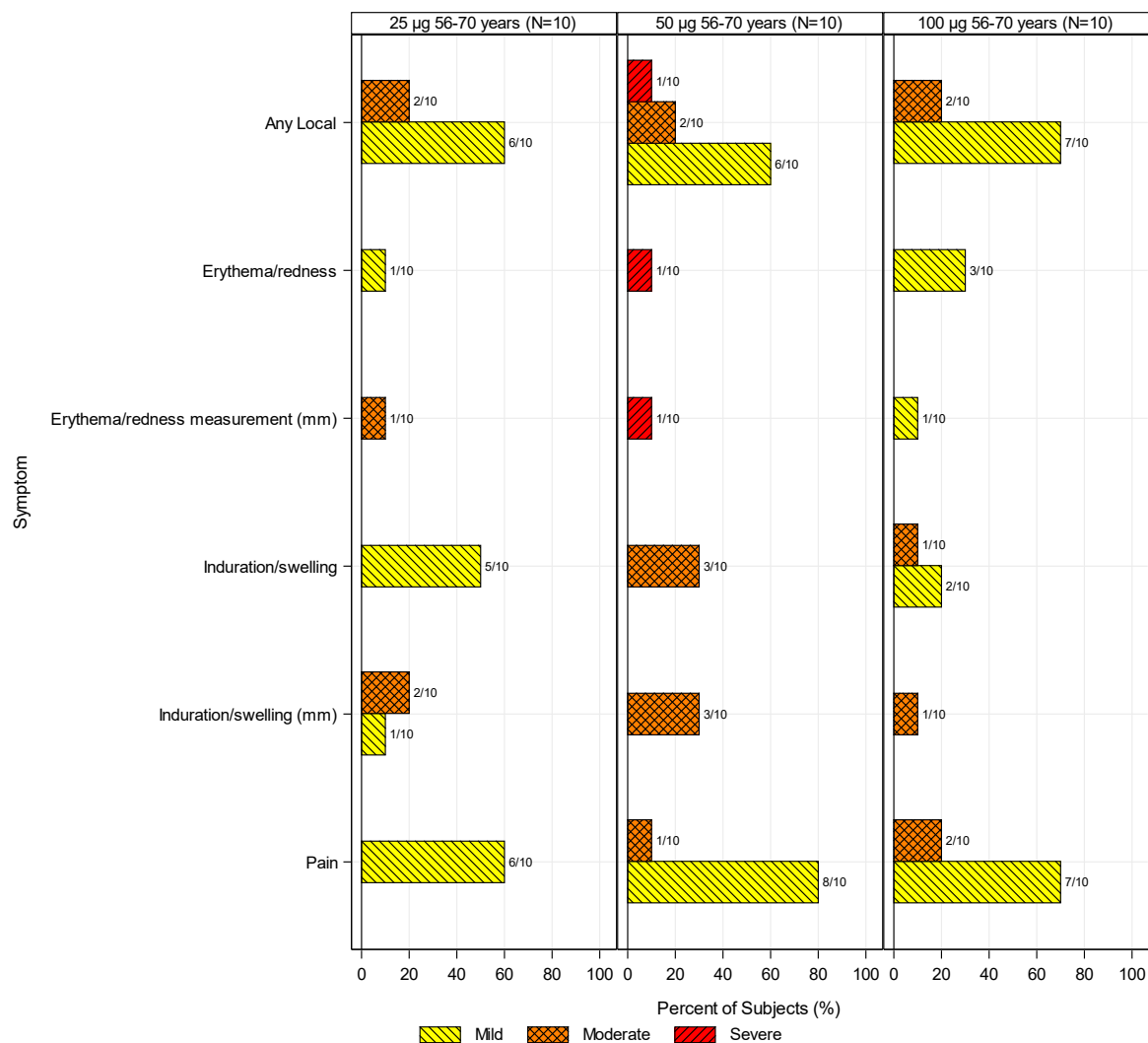
Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 1B(i):  
Maximum Severity of Solicited Events by Symptom and Vaccination Group - Systemic - 56-70 Years of Age**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

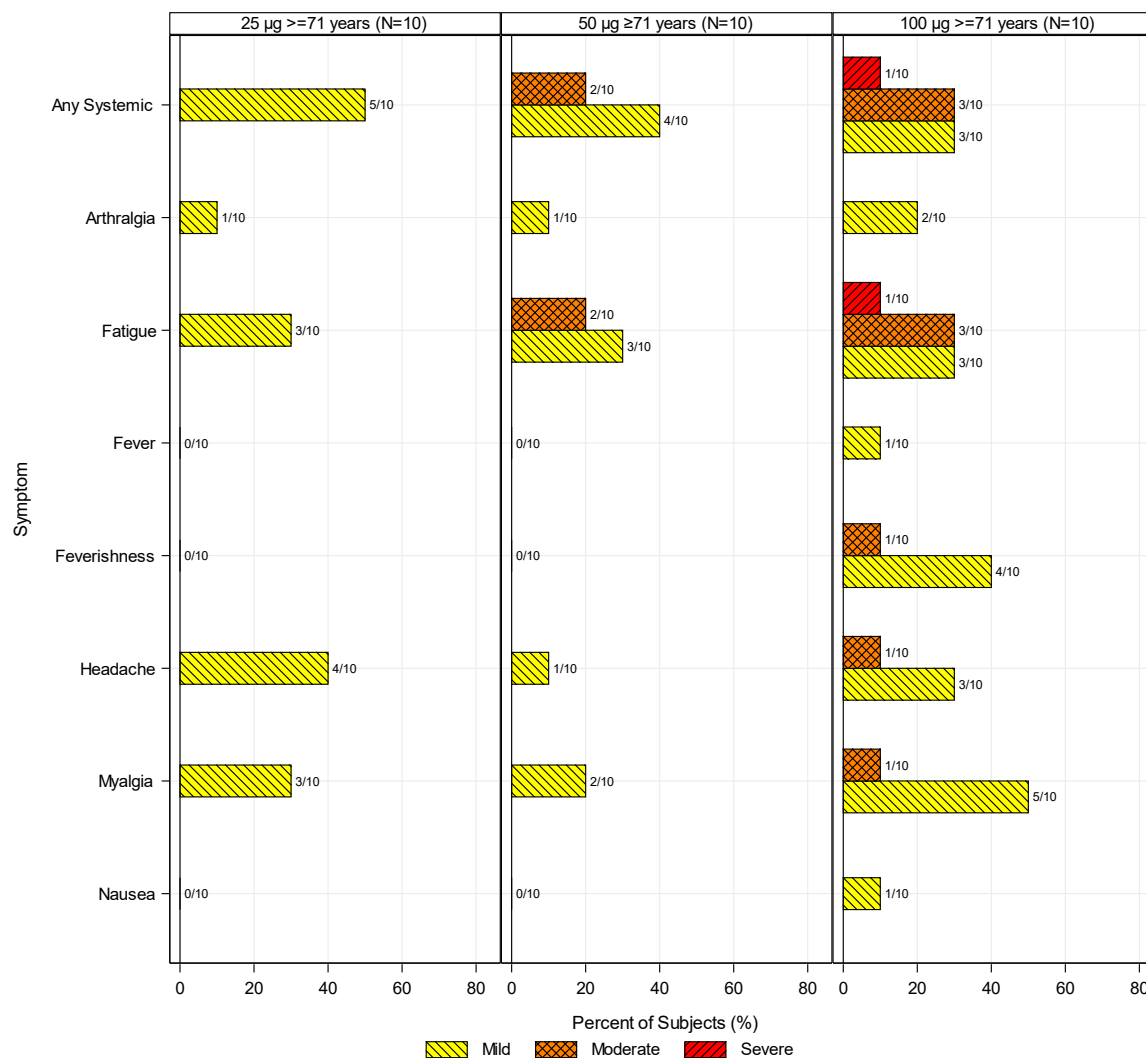
**FIGURE 1B(ii):  
Maximum Severity of Solicited Events by Symptom and Vaccination Group - Local - 56-70 Years of Age**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

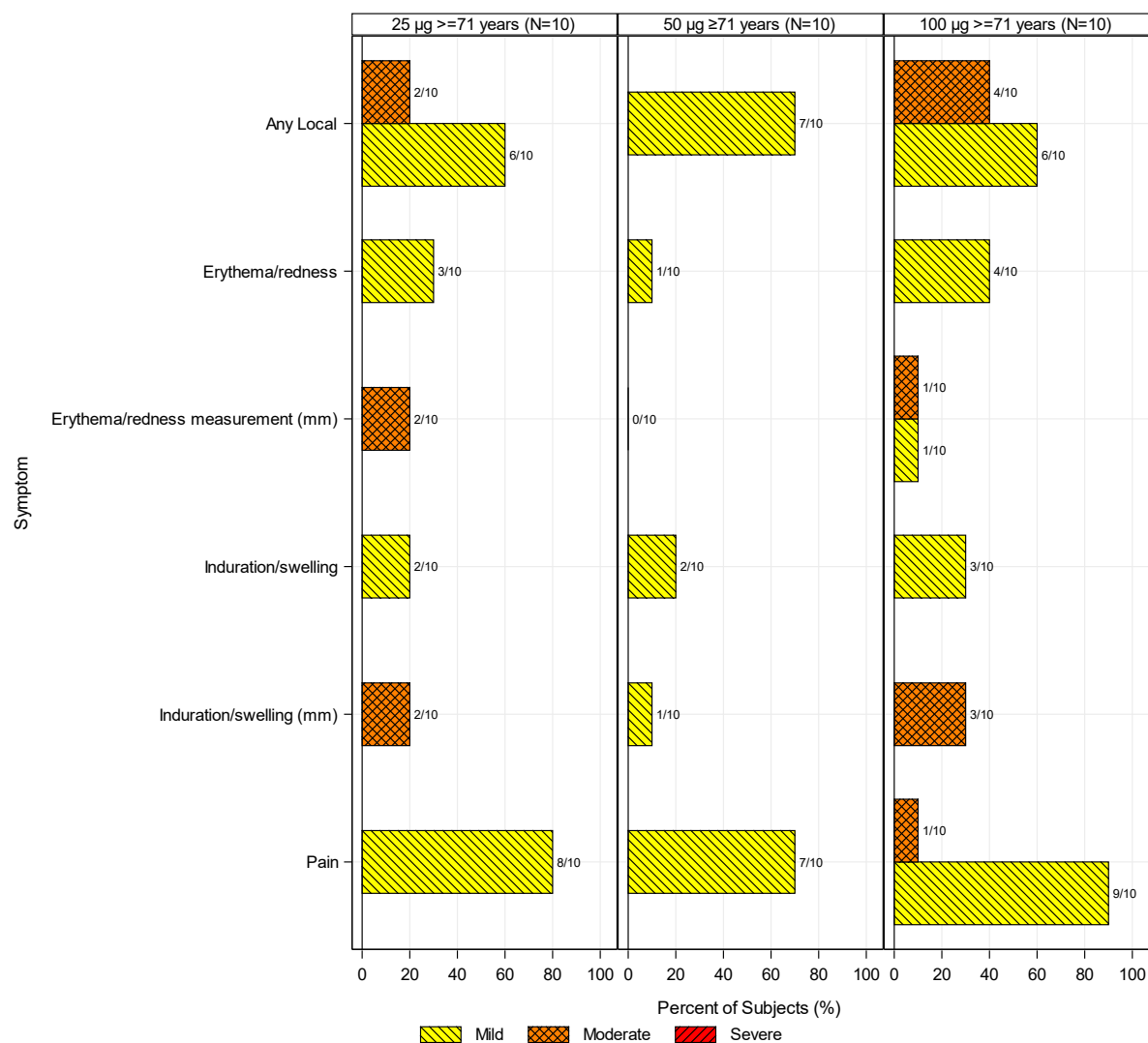


**FIGURE 1C(i):  
Maximum Severity of Solicited Events by Symptom and Vaccination Group - Systemic -  $\geq 71$  Years of Age**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 1C(ii):  
Maximum Severity of Solicited Events by Symptom and Vaccination Group - Local -  $\geq 71$  Years of Age**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 5A(i):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination**  
**Group - Any Symptom - 18-55 Years of Age**

|             |          |          | 25 µg<br>mRNA-1273<br>(N=15) |    | 50 µg<br>mRNA -1273<br>(N=15) |    | 100 µg<br>mRNA -1273<br>(N=15) |    | 250 µg<br>mRNA -1273<br>(N=15) |    | All Subjects<br>(N=60) |    |
|-------------|----------|----------|------------------------------|----|-------------------------------|----|--------------------------------|----|--------------------------------|----|------------------------|----|
| Symptom     | Dose     | Severity | n                            | %  | n                             | %  | n                              | %  | n                              | %  | n                      | %  |
| Any Symptom | Dose 1   | None     | 5                            | 33 | -                             | -  | 1                              | 7  | -                              | -  | 6                      | 10 |
|             |          | Mild     | 8                            | 53 | 9                             | 60 | 10                             | 67 | 9                              | 60 | 36                     | 60 |
|             |          | Moderate | 2                            | 13 | 6                             | 40 | 3                              | 20 | 5                              | 33 | 16                     | 27 |
|             |          | Severe   | -                            | -  | -                             | -  | 1                              | 7  | 1                              | 7  | 2                      | 3  |
|             | Dose 2   | None     | 3                            | 23 | -                             | -  | -                              | -  | -                              | -  | 3                      | 5  |
|             |          | Mild     | 7                            | 54 | 7                             | 47 | 3                              | 20 | 1                              | 7  | 18                     | 32 |
|             |          | Moderate | 3                            | 23 | 7                             | 47 | 11                             | 73 | 9                              | 64 | 30                     | 53 |
|             |          | Severe   | -                            | -  | 1                             | 7  | 1                              | 7  | 4                              | 29 | 6                      | 11 |
|             | Any Dose | None     | 4                            | 27 | -                             | -  | -                              | -  | -                              | -  | 4                      | 7  |
|             |          | Mild     | 6                            | 40 | 6                             | 40 | 3                              | 20 | 1                              | 7  | 16                     | 27 |
|             |          | Moderate | 5                            | 33 | 8                             | 53 | 11                             | 73 | 10                             | 67 | 34                     | 57 |
|             |          | Severe   | -                            | -  | 1                             | 7  | 1                              | 7  | 4                              | 27 | 6                      | 10 |

Severity is the maximum severity reported over all solicited symptoms post dosing for each subject.  
N=All subjects receiving Dose 1 with any solicited event data recorded in the database.

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 5A(ii):  
Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and  
Vaccination Group – Systemic Symptoms - 18-55 Years of Age**

|                      |          |          | 25 µg<br>mRNA-1273<br>(N=15) |     | 50 µg<br>mRNA -1273<br>(N=15) |    | 100 µg<br>mRNA -1273<br>(N=15) |    | 250 µg<br>mRNA -1273<br>(N=15) |    | All Subjects<br>(N=60) |    |
|----------------------|----------|----------|------------------------------|-----|-------------------------------|----|--------------------------------|----|--------------------------------|----|------------------------|----|
| Symptom              | Dose     | Severity | n                            | %   | n                             | %  | n                              | %  | n                              | %  | n                      | %  |
| Any Systemic Symptom | Dose 1   | None     | 10                           | 67  | 6                             | 40 | 5                              | 33 | 7                              | 47 | 28                     | 47 |
|                      |          | Mild     | 3                            | 20  | 6                             | 40 | 8                              | 53 | 4                              | 27 | 21                     | 35 |
|                      |          | Moderate | 2                            | 13  | 3                             | 20 | 2                              | 13 | 4                              | 27 | 11                     | 18 |
|                      |          | Severe   | -                            | -   | -                             | -  | -                              | -  | -                              | -  | -                      | -  |
|                      | Dose 2   | None     | 6                            | 46  | 2                             | 13 | -                              | -  | -                              | -  | 8                      | 14 |
|                      |          | Mild     | 4                            | 31  | 6                             | 40 | 3                              | 20 | 2                              | 14 | 15                     | 26 |
|                      |          | Moderate | 3                            | 23  | 6                             | 40 | 12                             | 80 | 9                              | 64 | 30                     | 53 |
|                      |          | Severe   | -                            | -   | 1                             | 7  | -                              | -  | 3                              | 21 | 4                      | 7  |
|                      | Any Dose | None     | 7                            | 47  | 2                             | 13 | -                              | -  | -                              | -  | 9                      | 15 |
|                      |          | Mild     | 3                            | 20  | 6                             | 40 | 3                              | 20 | 3                              | 20 | 15                     | 25 |
|                      |          | Moderate | 5                            | 33  | 6                             | 40 | 12                             | 80 | 9                              | 60 | 32                     | 53 |
|                      |          | Severe   | -                            | -   | 1                             | 7  | -                              | -  | 3                              | 20 | 4                      | 7  |
| Arthralgia           | Dose 1   | None     | 15                           | 100 | 13                            | 87 | 13                             | 87 | 14                             | 93 | 55                     | 92 |
|                      |          | Mild     | -                            | -   | 2                             | 13 | 1                              | 7  | 1                              | 7  | 4                      | 7  |
|                      |          | Moderate | -                            | -   | -                             | -  | 1                              | 7  | -                              | -  | 1                      | 2  |
|                      |          | Severe   | -                            | -   | -                             | -  | -                              | -  | -                              | -  | -                      | -  |
|                      | Dose 2   | None     | 11                           | 85  | 13                            | 87 | 13                             | 87 | 6                              | 43 | 43                     | 75 |
|                      |          | Mild     | -                            | -   | 1                             | 7  | 1                              | 7  | 5                              | 36 | 7                      | 12 |
|                      |          | Moderate | 2                            | 15  | 1                             | 7  | 1                              | 7  | 3                              | 21 | 7                      | 12 |
|                      |          | Severe   | -                            | -   | -                             | -  | -                              | -  | -                              | -  | -                      | -  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 5A(ii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Systemic Symptoms - 18-55 Years of Age** *(continued)*

|                    |          |          | 25 µg<br>mRNA-1273<br>(N=15) |     | 50 µg<br>mRNA -1273<br>(N=15) |     | 100 µg<br>mRNA -1273<br>(N=15) |     | 250 µg<br>mRNA -1273<br>(N=15) |     | All Subjects<br>(N=60) |     |
|--------------------|----------|----------|------------------------------|-----|-------------------------------|-----|--------------------------------|-----|--------------------------------|-----|------------------------|-----|
| Symptom            | Dose     | Severity | n                            | %   | n                             | %   | n                              | %   | n                              | %   | n                      | %   |
|                    | Any Dose | None     | 13                           | 87  | 12                            | 80  | 13                             | 87  | 7                              | 47  | 45                     | 75  |
|                    |          | Mild     | -                            | -   | 2                             | 13  | -                              | -   | 5                              | 33  | 7                      | 12  |
|                    |          | Moderate | 2                            | 13  | 1                             | 7   | 2                              | 13  | 3                              | 20  | 8                      | 13  |
|                    |          | Severe   | -                            | -   | -                             | -   | -                              | -   | -                              | -   | -                      | -   |
| Fatigue            | Dose 1   | None     | 11                           | 73  | 7                             | 47  | 11                             | 73  | 10                             | 67  | 39                     | 65  |
|                    |          | Mild     | 2                            | 13  | 5                             | 33  | 3                              | 20  | 3                              | 20  | 13                     | 22  |
|                    |          | Moderate | 2                            | 13  | 3                             | 20  | 1                              | 7   | 2                              | 13  | 8                      | 13  |
|                    |          | Severe   | -                            | -   | -                             | -   | -                              | -   | -                              | -   | -                      | -   |
|                    | Dose 2   | None     | 8                            | 62  | 5                             | 33  | 3                              | 20  | 4                              | 29  | 20                     | 35  |
|                    |          | Mild     | 4                            | 31  | 4                             | 27  | 6                              | 40  | 2                              | 14  | 16                     | 28  |
|                    |          | Moderate | 1                            | 8   | 6                             | 40  | 6                              | 40  | 6                              | 43  | 19                     | 33  |
|                    |          | Severe   | -                            | -   | -                             | -   | -                              | -   | 2                              | 14  | 2                      | 4   |
|                    | Any Dose | None     | 8                            | 53  | 5                             | 33  | 3                              | 20  | 5                              | 33  | 21                     | 35  |
|                    |          | Mild     | 4                            | 27  | 4                             | 27  | 5                              | 33  | 2                              | 13  | 15                     | 25  |
|                    |          | Moderate | 3                            | 20  | 6                             | 40  | 7                              | 47  | 6                              | 40  | 22                     | 37  |
|                    |          | Severe   | -                            | -   | -                             | -   | -                              | -   | 2                              | 13  | 2                      | 3   |
| Fever <sup>a</sup> | Dose 1   | None     | 15                           | 100 | 15                            | 100 | 15                             | 100 | 15                             | 100 | 60                     | 100 |
|                    |          | Mild     | -                            | -   | -                             | -   | -                              | -   | -                              | -   | -                      | -   |
|                    |          | Moderate | -                            | -   | -                             | -   | -                              | -   | -                              | -   | -                      | -   |
|                    |          | Severe   | -                            | -   | -                             | -   | -                              | -   | -                              | -   | -                      | -   |
|                    | Dose 2   | None     | 13                           | 100 | 14                            | 93  | 9                              | 60  | 6                              | 43  | 42                     | 74  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 5A(ii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Systemic Symptoms - 18-55 Years of Age** *(continued)*

|              |          |          | 25 µg<br>mRNA-1273<br>(N=15) |     | 50 µg<br>mRNA -1273<br>(N=15) |     | 100 µg<br>mRNA -1273<br>(N=15) |    | 250 µg<br>mRNA -1273<br>(N=15) |    | All Subjects<br>(N=60) |    |
|--------------|----------|----------|------------------------------|-----|-------------------------------|-----|--------------------------------|----|--------------------------------|----|------------------------|----|
| Symptom      | Dose     | Severity | n                            | %   | n                             | %   | n                              | %  | n                              | %  | n                      | %  |
|              |          | Mild     | -                            | -   | 1                             | 7   | 5                              | 33 | 5                              | 36 | 11                     | 19 |
|              |          | Moderate | -                            | -   | -                             | -   | 1                              | 7  | 2                              | 14 | 3                      | 5  |
|              |          | Severe   | -                            | -   | -                             | -   | -                              | -  | 1                              | 7  | 1                      | 2  |
|              | Any Dose | None     | 15                           | 100 | 14                            | 93  | 9                              | 60 | 7                              | 47 | 45                     | 75 |
|              |          | Mild     | -                            | -   | 1                             | 7   | 5                              | 33 | 5                              | 33 | 11                     | 18 |
|              |          | Moderate | -                            | -   | -                             | -   | 1                              | 7  | 2                              | 13 | 3                      | 5  |
|              |          | Severe   | -                            | -   | -                             | -   | -                              | -  | 1                              | 7  | 1                      | 2  |
| Feverishness | Dose 1   | None     | 15                           | 100 | 15                            | 100 | 14                             | 93 | 13                             | 87 | 57                     | 95 |
|              |          | Mild     | -                            | -   | -                             | -   | 1                              | 7  | 2                              | 13 | 3                      | 5  |
|              |          | Moderate | -                            | -   | -                             | -   | -                              | -  | -                              | -  | -                      | -  |
|              |          | Severe   | -                            | -   | -                             | -   | -                              | -  | -                              | -  | -                      | -  |
|              | Dose 2   | None     | 12                           | 92  | 12                            | 80  | 3                              | 20 | 2                              | 14 | 29                     | 51 |
|              |          | Mild     | 1                            | 8   | 2                             | 13  | 8                              | 53 | 4                              | 29 | 15                     | 26 |
|              |          | Moderate | -                            | -   | 1                             | 7   | 4                              | 27 | 5                              | 36 | 10                     | 18 |
|              |          | Severe   | -                            | -   | -                             | -   | -                              | -  | 3                              | 21 | 3                      | 5  |
|              | Any Dose | None     | 14                           | 93  | 12                            | 80  | 3                              | 20 | 3                              | 20 | 32                     | 53 |
|              |          | Mild     | 1                            | 7   | 2                             | 13  | 8                              | 53 | 4                              | 27 | 15                     | 25 |
|              |          | Moderate | -                            | -   | 1                             | 7   | 4                              | 27 | 5                              | 33 | 10                     | 17 |
|              |          | Severe   | -                            | -   | -                             | -   | -                              | -  | 3                              | 20 | 3                      | 5  |
| Headache     | Dose 1   | None     | 12                           | 80  | 12                            | 80  | 11                             | 73 | 8                              | 53 | 43                     | 72 |
|              |          | Mild     | 3                            | 20  | 3                             | 20  | 4                              | 27 | 4                              | 27 | 14                     | 23 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 5A(ii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Systemic Symptoms - 18-55 Years of Age** *(continued)*

|         |          |          | 25 µg<br>mRNA-1273<br>(N=15) |    | 50 µg<br>mRNA -1273<br>(N=15) |    | 100 µg<br>mRNA -1273<br>(N=15) |    | 250 µg<br>mRNA -1273<br>(N=15) |    | All Subjects<br>(N=60) |    |
|---------|----------|----------|------------------------------|----|-------------------------------|----|--------------------------------|----|--------------------------------|----|------------------------|----|
| Symptom | Dose     | Severity | n                            | %  | n                             | %  | n                              | %  | n                              | %  | n                      | %  |
|         |          | Moderate | -                            | -  | -                             | -  | -                              | -  | 3                              | 20 | 3                      | 5  |
|         |          | Severe   | -                            | -  | -                             | -  | -                              | -  | -                              | -  | -                      | -  |
|         | Dose 2   | None     | 10                           | 77 | 5                             | 33 | 6                              | 40 | -                              | -  | 21                     | 37 |
|         |          | Mild     | 2                            | 15 | 6                             | 40 | 5                              | 33 | 9                              | 64 | 22                     | 39 |
|         |          | Moderate | 1                            | 8  | 3                             | 20 | 4                              | 27 | 4                              | 29 | 12                     | 21 |
|         |          | Severe   | -                            | -  | 1                             | 7  | -                              | -  | 1                              | 7  | 2                      | 4  |
|         | Any Dose | None     | 11                           | 73 | 5                             | 33 | 5                              | 33 | -                              | -  | 21                     | 35 |
|         |          | Mild     | 3                            | 20 | 6                             | 40 | 6                              | 40 | 9                              | 60 | 24                     | 40 |
|         |          | Moderate | 1                            | 7  | 3                             | 20 | 4                              | 27 | 5                              | 33 | 13                     | 22 |
|         |          | Severe   | -                            | -  | 1                             | 7  | -                              | -  | 1                              | 7  | 2                      | 3  |
| Myalgia | Dose 1   | None     | 14                           | 93 | 13                            | 87 | 14                             | 93 | 11                             | 73 | 52                     | 87 |
|         |          | Mild     | 1                            | 7  | 2                             | 13 | 1                              | 7  | 4                              | 27 | 8                      | 13 |
|         |          | Moderate | -                            | -  | -                             | -  | -                              | -  | -                              | -  | -                      | -  |
|         |          | Severe   | -                            | -  | -                             | -  | -                              | -  | -                              | -  | -                      | -  |
|         | Dose 2   | None     | 10                           | 77 | 9                             | 60 | 7                              | 47 | 1                              | 7  | 27                     | 47 |
|         |          | Mild     | 2                            | 15 | 2                             | 13 | 2                              | 13 | 5                              | 36 | 11                     | 19 |
|         |          | Moderate | 1                            | 8  | 4                             | 27 | 6                              | 40 | 7                              | 50 | 18                     | 32 |
|         |          | Severe   | -                            | -  | -                             | -  | -                              | -  | 1                              | 7  | 1                      | 2  |
|         | Any Dose | None     | 11                           | 73 | 9                             | 60 | 7                              | 47 | 2                              | 13 | 29                     | 48 |
|         |          | Mild     | 3                            | 20 | 2                             | 13 | 2                              | 13 | 5                              | 33 | 12                     | 20 |
|         |          | Moderate | 1                            | 7  | 4                             | 27 | 6                              | 40 | 7                              | 47 | 18                     | 30 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 5A(ii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Systemic Symptoms - 18-55 Years of Age** *(continued)*

|         |          |          | 25 µg<br>mRNA-1273<br>(N=15) |    | 50 µg<br>mRNA -1273<br>(N=15) |    | 100 µg<br>mRNA -1273<br>(N=15) |     | 250 µg<br>mRNA -1273<br>(N=15) |    | All Subjects<br>(N=60) |    |
|---------|----------|----------|------------------------------|----|-------------------------------|----|--------------------------------|-----|--------------------------------|----|------------------------|----|
| Symptom | Dose     | Severity | n                            | %  | n                             | %  | n                              | %   | n                              | %  | n                      | %  |
|         |          | Severe   | -                            | -  | -                             | -  | -                              | -   | 1                              | 7  | 1                      | 2  |
| Nausea  | Dose 1   | None     | 14                           | 93 | 14                            | 93 | 15                             | 100 | 14                             | 93 | 57                     | 95 |
|         |          | Mild     | -                            | -  | -                             | -  | -                              | -   | 1                              | 7  | 1                      | 2  |
|         |          | Moderate | 1                            | 7  | 1                             | 7  | -                              | -   | -                              | -  | 2                      | 3  |
|         |          | Severe   | -                            | -  | -                             | -  | -                              | -   | -                              | -  | -                      | -  |
|         | Dose 2   | None     | 12                           | 92 | 13                            | 87 | 8                              | 53  | 10                             | 71 | 43                     | 75 |
|         |          | Mild     | 1                            | 8  | 2                             | 13 | 6                              | 40  | 1                              | 7  | 10                     | 18 |
|         |          | Moderate | -                            | -  | -                             | -  | 1                              | 7   | 2                              | 14 | 3                      | 5  |
|         |          | Severe   | -                            | -  | -                             | -  | -                              | -   | 1                              | 7  | 1                      | 2  |
|         | Any Dose | None     | 13                           | 87 | 13                            | 87 | 8                              | 53  | 11                             | 73 | 45                     | 75 |
|         |          | Mild     | 1                            | 7  | 1                             | 7  | 6                              | 40  | 1                              | 7  | 9                      | 15 |
|         |          | Moderate | 1                            | 7  | 1                             | 7  | 1                              | 7   | 2                              | 13 | 5                      | 8  |
|         |          | Severe   | -                            | -  | -                             | -  | -                              | -   | 1                              | 7  | 1                      | 2  |

Severity is the maximum severity reported over all solicited symptoms post dosing for each subject.

N=All subjects receiving Dose 1 with any solicited event data recorded in the database.

<sup>a</sup>Fever percentages reflect the number of subjects with at least one measurement available in the data system as the denominator. This denominator may differ from other systemic symptoms, which are solicited in-clinic at the post-dose assessment.



**TABLE 5A(iii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Local Symptoms - 18-55 Years of Age**

|                   |          |          | 25 µg<br>mRNA-1273<br>(N=15) |     | 50 µg<br>mRNA -1273<br>(N=15) |    | 100 µg<br>mRNA -1273<br>(N=15) |    | 250 µg<br>mRNA -1273<br>(N=15) |    | All Subjects<br>(N=60) |    |
|-------------------|----------|----------|------------------------------|-----|-------------------------------|----|--------------------------------|----|--------------------------------|----|------------------------|----|
| Symptom           | Dose     | Severity | n                            | %   | n                             | %  | n                              | %  | n                              | %  | n                      | %  |
| Any Local Symptom | Dose 1   | None     | 5                            | 33  | 2                             | 13 | 1                              | 7  | -                              | -  | 8                      | 13 |
|                   |          | Mild     | 10                           | 67  | 10                            | 67 | 11                             | 73 | 9                              | 60 | 40                     | 67 |
|                   |          | Moderate | -                            | -   | 3                             | 20 | 2                              | 13 | 5                              | 33 | 10                     | 17 |
|                   |          | Severe   | -                            | -   | -                             | -  | 1                              | 7  | 1                              | 7  | 2                      | 3  |
|                   | Dose 2   | None     | 3                            | 23  | 1                             | 7  | -                              | -  | -                              | -  | 4                      | 7  |
|                   |          | Mild     | 9                            | 69  | 11                            | 73 | 10                             | 67 | 7                              | 50 | 37                     | 65 |
|                   |          | Moderate | 1                            | 8   | 3                             | 20 | 4                              | 27 | 6                              | 43 | 14                     | 25 |
|                   |          | Severe   | -                            | -   | -                             | -  | 1                              | 7  | 1                              | 7  | 2                      | 4  |
|                   | Any Dose | None     | 4                            | 27  | 1                             | 7  | -                              | -  | -                              | -  | 5                      | 8  |
|                   |          | Mild     | 10                           | 67  | 10                            | 67 | 9                              | 60 | 6                              | 40 | 35                     | 58 |
|                   |          | Moderate | 1                            | 7   | 4                             | 27 | 5                              | 33 | 8                              | 53 | 18                     | 30 |
|                   |          | Severe   | -                            | -   | -                             | -  | 1                              | 7  | 1                              | 7  | 2                      | 3  |
| Erythema/Redness  | Dose 1   | None     | 15                           | 100 | 14                            | 93 | 13                             | 87 | 13                             | 87 | 55                     | 92 |
|                   |          | Mild     | -                            | -   | 1                             | 7  | 2                              | 13 | 2                              | 13 | 5                      | 8  |
|                   |          | Moderate | -                            | -   | -                             | -  | -                              | -  | -                              | -  | -                      | -  |
|                   |          | Severe   | -                            | -   | -                             | -  | -                              | -  | -                              | -  | -                      | -  |
|                   | Dose 2   | None     | 12                           | 92  | 11                            | 73 | 13                             | 87 | 11                             | 79 | 47                     | 82 |
|                   |          | Mild     | 1                            | 8   | 4                             | 27 | 2                              | 13 | 3                              | 21 | 10                     | 18 |
|                   |          | Moderate | -                            | -   | -                             | -  | -                              | -  | -                              | -  | -                      | -  |
|                   |          | Severe   | -                            | -   | -                             | -  | -                              | -  | -                              | -  | -                      | -  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 5A(iii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Local Symptoms - 18-55 Years of Age** *(continued)*

|                                   |          |          | 25 µg<br>mRNA-1273<br>(N=15) |     | 50 µg<br>mRNA -1273<br>(N=15) |     | 100 µg<br>mRNA -1273<br>(N=15) |    | 250 µg<br>mRNA -1273<br>(N=15) |    | All Subjects<br>(N=60) |    |
|-----------------------------------|----------|----------|------------------------------|-----|-------------------------------|-----|--------------------------------|----|--------------------------------|----|------------------------|----|
| Symptom                           | Dose     | Severity | n                            | %   | n                             | %   | n                              | %  | n                              | %  | n                      | %  |
|                                   | Any Dose | None     | 14                           | 93  | 11                            | 73  | 13                             | 87 | 11                             | 73 | 49                     | 82 |
|                                   |          | Mild     | 1                            | 7   | 4                             | 27  | 2                              | 13 | 4                              | 27 | 11                     | 18 |
|                                   |          | Moderate | -                            | -   | -                             | -   | -                              | -  | -                              | -  | -                      | -  |
|                                   |          | Severe   | -                            | -   | -                             | -   | -                              | -  | -                              | -  | -                      | -  |
| Erythema/Redness Measurement (mm) | Dose 1   | None     | 15                           | 100 | 15                            | 100 | 13                             | 87 | 14                             | 93 | 57                     | 95 |
|                                   |          | Mild     | -                            | -   | -                             | -   | -                              | -  | -                              | -  | -                      | -  |
|                                   |          | Moderate | -                            | -   | -                             | -   | 1                              | 7  | -                              | -  | 1                      | 2  |
|                                   |          | Severe   | -                            | -   | -                             | -   | 1                              | 7  | 1                              | 7  | 2                      | 3  |
|                                   | Dose 2   | None     | 13                           | 100 | 15                            | 100 | 13                             | 87 | 11                             | 79 | 52                     | 91 |
|                                   |          | Mild     | -                            | -   | -                             | -   | 1                              | 7  | -                              | -  | 1                      | 2  |
|                                   |          | Moderate | -                            | -   | -                             | -   | -                              | -  | 2                              | 14 | 2                      | 4  |
|                                   |          | Severe   | -                            | -   | -                             | -   | 1                              | 7  | 1                              | 7  | 2                      | 4  |
|                                   | Any Dose | None     | 15                           | 100 | 15                            | 100 | 13                             | 87 | 12                             | 80 | 55                     | 92 |
|                                   |          | Mild     | -                            | -   | -                             | -   | -                              | -  | -                              | -  | -                      | -  |
|                                   |          | Moderate | -                            | -   | -                             | -   | 1                              | 7  | 2                              | 13 | 3                      | 5  |
|                                   |          | Severe   | -                            | -   | -                             | -   | 1                              | 7  | 1                              | 7  | 2                      | 3  |
| Induration/Swelling               | Dose 1   | None     | 15                           | 100 | 12                            | 80  | 12                             | 80 | 11                             | 73 | 50                     | 83 |
|                                   |          | Mild     | -                            | -   | 3                             | 20  | 3                              | 20 | 3                              | 20 | 9                      | 15 |
|                                   |          | Moderate | -                            | -   | -                             | -   | -                              | -  | 1                              | 7  | 1                      | 2  |
|                                   |          | Severe   | -                            | -   | -                             | -   | -                              | -  | -                              | -  | -                      | -  |

**TABLE 5A(iii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Local Symptoms - 18-55 Years of Age** *(continued)*

|                          |          |          | 25 µg<br>mRNA-1273<br>(N=15) |     | 50 µg<br>mRNA -1273<br>(N=15) |     | 100 µg<br>mRNA -1273<br>(N=15) |    | 250 µg<br>mRNA -1273<br>(N=15) |    | All Subjects<br>(N=60) |    |
|--------------------------|----------|----------|------------------------------|-----|-------------------------------|-----|--------------------------------|----|--------------------------------|----|------------------------|----|
| Symptom                  | Dose     | Severity | n                            | %   | n                             | %   | n                              | %  | n                              | %  | n                      | %  |
|                          | Dose 2   | None     | 13                           | 100 | 15                            | 100 | 14                             | 93 | 11                             | 79 | 53                     | 93 |
|                          |          | Mild     | -                            | -   | -                             | -   | 1                              | 7  | 2                              | 14 | 3                      | 5  |
|                          |          | Moderate | -                            | -   | -                             | -   | -                              | -  | 1                              | 7  | 1                      | 2  |
|                          |          | Severe   | -                            | -   | -                             | -   | -                              | -  | -                              | -  | -                      | -  |
|                          | Any Dose | None     | 15                           | 100 | 12                            | 80  | 12                             | 80 | 11                             | 73 | 50                     | 83 |
|                          |          | Mild     | -                            | -   | 3                             | 20  | 3                              | 20 | 3                              | 20 | 9                      | 15 |
|                          |          | Moderate | -                            | -   | -                             | -   | -                              | -  | 1                              | 7  | 1                      | 2  |
|                          |          | Severe   | -                            | -   | -                             | -   | -                              | -  | -                              | -  | -                      | -  |
| Induration/Swelling (mm) | Dose 1   | None     | 15                           | 100 | 14                            | 93  | 13                             | 87 | 12                             | 80 | 54                     | 90 |
|                          |          | Mild     | -                            | -   | -                             | -   | 2                              | 13 | 1                              | 7  | 3                      | 5  |
|                          |          | Moderate | -                            | -   | 1                             | 7   | -                              | -  | 1                              | 7  | 2                      | 3  |
|                          |          | Severe   | -                            | -   | -                             | -   | -                              | -  | 1                              | 7  | 1                      | 2  |
|                          | Dose 2   | None     | 13                           | 100 | 15                            | 100 | 14                             | 93 | 11                             | 79 | 53                     | 93 |
|                          |          | Mild     | -                            | -   | -                             | -   | -                              | -  | 1                              | 7  | 1                      | 2  |
|                          |          | Moderate | -                            | -   | -                             | -   | 1                              | 7  | 2                              | 14 | 3                      | 5  |
|                          |          | Severe   | -                            | -   | -                             | -   | -                              | -  | -                              | -  | -                      | -  |
|                          | Any Dose | None     | 15                           | 100 | 14                            | 93  | 13                             | 87 | 11                             | 73 | 53                     | 88 |
|                          |          | Mild     | -                            | -   | -                             | -   | 1                              | 7  | 2                              | 13 | 3                      | 5  |
|                          |          | Moderate | -                            | -   | 1                             | 7   | 1                              | 7  | 1                              | 7  | 3                      | 5  |
|                          |          | Severe   | -                            | -   | -                             | -   | -                              | -  | 1                              | 7  | 1                      | 2  |

**TABLE 5A(iii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Local Symptoms - 18-55 Years of Age** *(continued)*

| Symptom | Dose     | Severity | 25 µg<br>mRNA-1273<br>(N=15) |    | 50 µg<br>mRNA -1273<br>(N=15) |    | 100 µg<br>mRNA -1273<br>(N=15) |    | 250 µg<br>mRNA -1273<br>(N=15) |    | All Subjects<br>(N=60) |    |
|---------|----------|----------|------------------------------|----|-------------------------------|----|--------------------------------|----|--------------------------------|----|------------------------|----|
|         |          |          | n                            | %  | n                             | %  | n                              | %  | n                              | %  | n                      | %  |
| Pain    | Dose 1   | None     | 5                            | 33 | 2                             | 13 | 1                              | 7  | -                              | -  | 8                      | 13 |
|         |          | Mild     | 10                           | 67 | 11                            | 73 | 12                             | 80 | 9                              | 60 | 42                     | 70 |
|         |          | Moderate | -                            | -  | 2                             | 13 | 2                              | 13 | 6                              | 40 | 10                     | 17 |
|         |          | Severe   | -                            | -  | -                             | -  | -                              | -  | -                              | -  | -                      | -  |
|         | Dose 2   | None     | 3                            | 23 | 2                             | 13 | -                              | -  | -                              | -  | 5                      | 9  |
|         |          | Mild     | 9                            | 69 | 10                            | 67 | 11                             | 73 | 10                             | 71 | 40                     | 70 |
|         |          | Moderate | 1                            | 8  | 3                             | 20 | 4                              | 27 | 4                              | 29 | 12                     | 21 |
|         |          | Severe   | -                            | -  | -                             | -  | -                              | -  | -                              | -  | -                      | -  |
|         | Any Dose | None     | 4                            | 27 | 1                             | 7  | -                              | -  | -                              | -  | 5                      | 8  |
|         |          | Mild     | 10                           | 67 | 10                            | 67 | 10                             | 67 | 8                              | 53 | 38                     | 63 |
|         |          | Moderate | 1                            | 7  | 4                             | 27 | 5                              | 33 | 7                              | 47 | 17                     | 28 |
|         |          | Severe   | -                            | -  | -                             | -  | -                              | -  | -                              | -  | -                      | -  |

Severity is the maximum severity reported over all solicited symptoms post dosing for each subject.

N=All subjects receiving Dose 1 with any solicited event data recorded in the database.

**TABLE 5B(i):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Any Symptom - 56-70 Years of Age**

| Symptom     | Dose     | Severity | 25 µg<br>mRNA-1273<br>(N=10) |    | 50 µg<br>mRNA-1273<br>(N=10) |    | 100 µg<br>mRNA-1273<br>(N=10) |    | All Subjects<br>(N=30) |    |
|-------------|----------|----------|------------------------------|----|------------------------------|----|-------------------------------|----|------------------------|----|
|             |          |          | n                            | %  | n                            | %  | n                             | %  | n                      | %  |
| Any Symptom | Dose 1   | None     | 3                            | 30 | 4                            | 40 | 1                             | 10 | 8                      | 27 |
|             |          | Mild     | 5                            | 50 | 4                            | 40 | 9                             | 90 | 18                     | 60 |
|             |          | Moderate | 2                            | 20 | 2                            | 20 | -                             | -  | 4                      | 13 |
|             |          | Severe   | -                            | -  | -                            | -  | -                             | -  | -                      | -  |
|             | Dose 2   | None     | -                            | -  | 2                            | 20 | 1                             | 11 | 3                      | 10 |
|             |          | Mild     | 6                            | 60 | 7                            | 70 | 3                             | 33 | 16                     | 55 |
|             |          | Moderate | 3                            | 30 | -                            | -  | 5                             | 56 | 8                      | 28 |
|             |          | Severe   | 1                            | 10 | 1                            | 10 | -                             | -  | 2                      | 7  |
|             | Any Dose | None     | -                            | -  | 1                            | 10 | 1                             | 10 | 2                      | 7  |
|             |          | Mild     | 4                            | 40 | 6                            | 60 | 4                             | 40 | 14                     | 47 |
|             |          | Moderate | 5                            | 50 | 2                            | 20 | 5                             | 50 | 12                     | 40 |
|             |          | Severe   | 1                            | 10 | 1                            | 10 | -                             | -  | 2                      | 7  |

Severity is the maximum severity reported over all solicited symptoms post dosing for each subject.

N=All subjects receiving Dose 1 with any solicited event data recorded in the database.

**TABLE 5B(ii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Systemic Symptoms - 56-70 Years of Age**

|                      |          |          | 25 µg<br>mRNA-1273<br>(N=10) |    | 50 µg<br>mRNA-1273<br>(N=10) |     | 100 µg<br>mRNA-1273<br>(N=10) |     | All Subjects<br>(N=30) |    |
|----------------------|----------|----------|------------------------------|----|------------------------------|-----|-------------------------------|-----|------------------------|----|
| Symptom              | Dose     | Severity | n                            | %  | n                            | %   | n                             | %   | n                      | %  |
| Any Systemic Symptom | Dose 1   | None     | 5                            | 50 | 7                            | 70  | 7                             | 70  | 19                     | 63 |
|                      |          | Mild     | 3                            | 30 | 2                            | 20  | 3                             | 30  | 8                      | 27 |
|                      |          | Moderate | 2                            | 20 | 1                            | 10  | -                             | -   | 3                      | 10 |
|                      |          | Severe   | -                            | -  | -                            | -   | -                             | -   | -                      | -  |
|                      | Dose 2   | None     | 3                            | 30 | 5                            | 50  | 1                             | 11  | 9                      | 31 |
|                      |          | Mild     | 5                            | 50 | 4                            | 40  | 3                             | 33  | 12                     | 41 |
|                      |          | Moderate | 1                            | 10 | 1                            | 10  | 5                             | 56  | 7                      | 24 |
|                      |          | Severe   | 1                            | 10 | -                            | -   | -                             | -   | 1                      | 3  |
|                      | Any Dose | None     | 2                            | 20 | 4                            | 40  | 2                             | 20  | 8                      | 27 |
|                      |          | Mild     | 4                            | 40 | 4                            | 40  | 3                             | 30  | 11                     | 37 |
|                      |          | Moderate | 3                            | 30 | 2                            | 20  | 5                             | 50  | 10                     | 33 |
|                      |          | Severe   | 1                            | 10 | -                            | -   | -                             | -   | 1                      | 3  |
| Arthralgia           | Dose 1   | None     | 7                            | 70 | 10                           | 100 | 10                            | 100 | 27                     | 90 |
|                      |          | Mild     | 1                            | 10 | -                            | -   | -                             | -   | 1                      | 3  |
|                      |          | Moderate | 2                            | 20 | -                            | -   | -                             | -   | 2                      | 7  |
|                      |          | Severe   | -                            | -  | -                            | -   | -                             | -   | -                      | -  |
|                      | Dose 2   | None     | 9                            | 90 | 9                            | 90  | 7                             | 78  | 25                     | 86 |
|                      |          | Mild     | -                            | -  | 1                            | 10  | 1                             | 11  | 2                      | 7  |
|                      |          | Moderate | 1                            | 10 | -                            | -   | 1                             | 11  | 2                      | 7  |
|                      |          | Severe   | -                            | -  | -                            | -   | -                             | -   | -                      | -  |

**TABLE 5B(ii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Systemic Symptoms - 56-70 Years of Age** *(continued)*

|                    |          |          | 25 µg<br>mRNA-1273<br>(N=10) |     | 50 µg<br>mRNA-1273<br>(N=10) |     | 100 µg<br>mRNA-1273<br>(N=10) |     | All Subjects<br>(N=30) |     |
|--------------------|----------|----------|------------------------------|-----|------------------------------|-----|-------------------------------|-----|------------------------|-----|
| Symptom            | Dose     | Severity | n                            | %   | n                            | %   | n                             | %   | n                      | %   |
| Fatigue            | Any Dose | None     | 6                            | 60  | 9                            | 90  | 8                             | 80  | 23                     | 77  |
|                    |          | Mild     | 1                            | 10  | 1                            | 10  | 1                             | 10  | 3                      | 10  |
|                    |          | Moderate | 3                            | 30  | -                            | -   | 1                             | 10  | 4                      | 13  |
|                    |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                    | Dose 1   | None     | 8                            | 80  | 9                            | 90  | 7                             | 70  | 24                     | 80  |
|                    |          | Mild     | 2                            | 20  | 1                            | 10  | 3                             | 30  | 6                      | 20  |
|                    |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                    |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                    | Dose 2   | None     | 6                            | 60  | 5                            | 50  | 2                             | 22  | 13                     | 45  |
|                    |          | Mild     | 2                            | 20  | 4                            | 40  | 2                             | 22  | 8                      | 28  |
|                    |          | Moderate | 2                            | 20  | 1                            | 10  | 5                             | 56  | 8                      | 28  |
|                    |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                    | Any Dose | None     | 6                            | 60  | 5                            | 50  | 3                             | 30  | 14                     | 47  |
|                    |          | Mild     | 2                            | 20  | 4                            | 40  | 2                             | 20  | 8                      | 27  |
|                    |          | Moderate | 2                            | 20  | 1                            | 10  | 5                             | 50  | 8                      | 27  |
|                    |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
| Fever <sup>a</sup> | Dose 1   | None     | 10                           | 100 | 10                           | 100 | 10                            | 100 | 30                     | 100 |
|                    |          | Mild     | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                    |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                    |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |

**TABLE 5B(ii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Systemic Symptoms - 56-70 Years of Age (continued)**

|              |          |          | 25 µg<br>mRNA-1273<br>(N=10) |     | 50 µg<br>mRNA-1273<br>(N=10) |     | 100 µg<br>mRNA-1273<br>(N=10) |     | All Subjects<br>(N=30) |     |
|--------------|----------|----------|------------------------------|-----|------------------------------|-----|-------------------------------|-----|------------------------|-----|
| Symptom      | Dose     | Severity | n                            | %   | n                            | %   | n                             | %   | n                      | %   |
|              | Dose 2   | None     | 9                            | 90  | 9                            | 90  | 8                             | 89  | 26                     | 90  |
|              |          | Mild     | -                            | -   | 1                            | 10  | 1                             | 11  | 2                      | 7   |
|              |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|              |          | Severe   | 1                            | 10  | -                            | -   | -                             | -   | 1                      | 3   |
|              | Any Dose | None     | 9                            | 90  | 9                            | 90  | 9                             | 90  | 27                     | 90  |
|              |          | Mild     | -                            | -   | 1                            | 10  | 1                             | 10  | 2                      | 7   |
|              |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|              |          | Severe   | 1                            | 10  | -                            | -   | -                             | -   | 1                      | 3   |
| Feverishness | Dose 1   | None     | 10                           | 100 | 10                           | 100 | 10                            | 100 | 30                     | 100 |
|              |          | Mild     | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|              |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|              |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|              | Dose 2   | None     | 8                            | 80  | 8                            | 80  | 4                             | 44  | 20                     | 69  |
|              |          | Mild     | 1                            | 10  | 1                            | 10  | 3                             | 33  | 5                      | 17  |
|              |          | Moderate | 1                            | 10  | 1                            | 10  | 2                             | 22  | 4                      | 14  |
|              |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|              | Any Dose | None     | 8                            | 80  | 8                            | 80  | 5                             | 50  | 21                     | 70  |
|              |          | Mild     | 1                            | 10  | 1                            | 10  | 3                             | 30  | 5                      | 17  |
|              |          | Moderate | 1                            | 10  | 1                            | 10  | 2                             | 20  | 4                      | 13  |
|              |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |



**TABLE 5B(ii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Systemic Symptoms - 56-70 Years of Age** *(continued)*

| Symptom  | Dose     | Severity | 25 µg<br>mRNA-1273<br>(N=10) |    | 50 µg<br>mRNA-1273<br>(N=10) |    | 100 µg<br>mRNA-1273<br>(N=10) |     | All Subjects<br>(N=30) |    |
|----------|----------|----------|------------------------------|----|------------------------------|----|-------------------------------|-----|------------------------|----|
|          |          |          | n                            | %  | n                            | %  | n                             | %   | n                      | %  |
| Headache | Dose 1   | None     | 8                            | 80 | 9                            | 90 | 10                            | 100 | 27                     | 90 |
|          |          | Mild     | 2                            | 20 | 1                            | 10 | -                             | -   | 3                      | 10 |
|          |          | Moderate | -                            | -  | -                            | -  | -                             | -   | -                      | -  |
|          |          | Severe   | -                            | -  | -                            | -  | -                             | -   | -                      | -  |
|          | Dose 2   | None     | 7                            | 70 | 7                            | 70 | 2                             | 22  | 16                     | 55 |
|          |          | Mild     | 2                            | 20 | 3                            | 30 | 6                             | 67  | 11                     | 38 |
|          |          | Moderate | 1                            | 10 | -                            | -  | 1                             | 11  | 2                      | 7  |
|          |          | Severe   | -                            | -  | -                            | -  | -                             | -   | -                      | -  |
|          | Any Dose | None     | 6                            | 60 | 7                            | 70 | 3                             | 30  | 16                     | 53 |
|          |          | Mild     | 3                            | 30 | 3                            | 30 | 6                             | 60  | 12                     | 40 |
|          |          | Moderate | 1                            | 10 | -                            | -  | 1                             | 10  | 2                      | 7  |
|          |          | Severe   | -                            | -  | -                            | -  | -                             | -   | -                      | -  |
| Myalgia  | Dose 1   | None     | 8                            | 80 | 9                            | 90 | 9                             | 90  | 26                     | 87 |
|          |          | Mild     | 2                            | 20 | 1                            | 10 | 1                             | 10  | 4                      | 13 |
|          |          | Moderate | -                            | -  | -                            | -  | -                             | -   | -                      | -  |
|          |          | Severe   | -                            | -  | -                            | -  | -                             | -   | -                      | -  |
|          | Dose 2   | None     | 4                            | 40 | 8                            | 80 | 2                             | 22  | 14                     | 48 |
|          |          | Mild     | 5                            | 50 | 2                            | 20 | 3                             | 33  | 10                     | 34 |
|          |          | Moderate | 1                            | 10 | -                            | -  | 4                             | 44  | 5                      | 17 |
|          |          | Severe   | -                            | -  | -                            | -  | -                             | -   | -                      | -  |

**TABLE 5B(ii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Systemic Symptoms - 56-70 Years of Age** *(continued)*

| Symptom | Dose     | Severity | 25 µg<br>mRNA-1273<br>(N=10) |     | 50 µg<br>mRNA-1273<br>(N=10) |     | 100 µg<br>mRNA-1273<br>(N=10) |     | All Subjects<br>(N=30) |    |
|---------|----------|----------|------------------------------|-----|------------------------------|-----|-------------------------------|-----|------------------------|----|
|         |          |          | n                            | %   | n                            | %   | n                             | %   | n                      | %  |
|         | Any Dose | None     | 4                            | 40  | 7                            | 70  | 3                             | 30  | 14                     | 47 |
|         |          | Mild     | 5                            | 50  | 3                            | 30  | 3                             | 30  | 11                     | 37 |
|         |          | Moderate | 1                            | 10  | -                            | -   | 4                             | 40  | 5                      | 17 |
|         |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -  |
| Nausea  | Dose 1   | None     | 10                           | 100 | 8                            | 80  | 10                            | 100 | 28                     | 93 |
|         |          | Mild     | -                            | -   | 1                            | 10  | -                             | -   | 1                      | 3  |
|         |          | Moderate | -                            | -   | 1                            | 10  | -                             | -   | 1                      | 3  |
|         |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -  |
|         | Dose 2   | None     | 8                            | 80  | 10                           | 100 | 5                             | 56  | 23                     | 79 |
|         |          | Mild     | 2                            | 20  | -                            | -   | 2                             | 22  | 4                      | 14 |
|         |          | Moderate | -                            | -   | -                            | -   | 2                             | 22  | 2                      | 7  |
|         |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -  |
|         | Any Dose | None     | 8                            | 80  | 8                            | 80  | 6                             | 60  | 22                     | 73 |
|         |          | Mild     | 2                            | 20  | 1                            | 10  | 2                             | 20  | 5                      | 17 |
|         |          | Moderate | -                            | -   | 1                            | 10  | 2                             | 20  | 3                      | 10 |
|         |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -  |

Severity is the maximum severity reported over all solicited symptoms post dosing for each subject.

N=All subjects receiving Dose 1 with any solicited event data recorded in the database.

<sup>a</sup>Fever percentages reflect the number of subjects with at least one measurement available in the data system as the denominator. This denominator may differ from other systemic symptoms, which are solicited in-clinic at the post-dose assessment.

**TABLE 5B(iii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Local Symptoms - 56-70 Years of Age**

|                   |          |          | 25 µg<br>mRNA-1273<br>(N=10) |    | 50 µg<br>mRNA-1273<br>(N=10) |     | 100 µg<br>mRNA-1273<br>(N=10) |    | All Subjects<br>(N=30) |    |
|-------------------|----------|----------|------------------------------|----|------------------------------|-----|-------------------------------|----|------------------------|----|
| Symptom           | Dose     | Severity | n                            | %  | n                            | %   | n                             | %  | n                      | %  |
| Any Local Symptom | Dose 1   | None     | 5                            | 50 | 4                            | 40  | 2                             | 20 | 11                     | 37 |
|                   |          | Mild     | 5                            | 50 | 4                            | 40  | 8                             | 80 | 17                     | 57 |
|                   |          | Moderate | -                            | -  | 2                            | 20  | -                             | -  | 2                      | 7  |
|                   |          | Severe   | -                            | -  | -                            | -   | -                             | -  | -                      | -  |
|                   | Dose 2   | None     | 4                            | 40 | 2                            | 20  | 1                             | 11 | 7                      | 24 |
|                   |          | Mild     | 4                            | 40 | 7                            | 70  | 6                             | 67 | 17                     | 59 |
|                   |          | Moderate | 2                            | 20 | -                            | -   | 2                             | 22 | 4                      | 14 |
|                   |          | Severe   | -                            | -  | 1                            | 10  | -                             | -  | 1                      | 3  |
|                   | Any Dose | None     | 2                            | 20 | 1                            | 10  | 1                             | 10 | 4                      | 13 |
|                   |          | Mild     | 6                            | 60 | 6                            | 60  | 7                             | 70 | 19                     | 63 |
|                   |          | Moderate | 2                            | 20 | 2                            | 20  | 2                             | 20 | 6                      | 20 |
|                   |          | Severe   | -                            | -  | 1                            | 10  | -                             | -  | 1                      | 3  |
| Erythema/Redness  | Dose 1   | None     | 9                            | 90 | 10                           | 100 | 9                             | 90 | 28                     | 93 |
|                   |          | Mild     | 1                            | 10 | -                            | -   | 1                             | 10 | 2                      | 7  |
|                   |          | Moderate | -                            | -  | -                            | -   | -                             | -  | -                      | -  |
|                   |          | Severe   | -                            | -  | -                            | -   | -                             | -  | -                      | -  |
|                   | Dose 2   | None     | 9                            | 90 | 9                            | 90  | 7                             | 78 | 25                     | 86 |
|                   |          | Mild     | 1                            | 10 | -                            | -   | 2                             | 22 | 3                      | 10 |
|                   |          | Moderate | -                            | -  | -                            | -   | -                             | -  | -                      | -  |
|                   |          | Severe   | -                            | -  | 1                            | 10  | -                             | -  | 1                      | 3  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 5B(iii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Local Symptoms - 56-70 Years of Age** *(continued)*

|                                   |          |          | 25 µg<br>mRNA-1273<br>(N=10) |     | 50 µg<br>mRNA-1273<br>(N=10) |     | 100 µg<br>mRNA-1273<br>(N=10) |     | All Subjects<br>(N=30) |     |
|-----------------------------------|----------|----------|------------------------------|-----|------------------------------|-----|-------------------------------|-----|------------------------|-----|
| Symptom                           | Dose     | Severity | n                            | %   | n                            | %   | n                             | %   | n                      | %   |
|                                   | Any Dose | None     | 9                            | 90  | 9                            | 90  | 7                             | 70  | 25                     | 83  |
|                                   |          | Mild     | 1                            | 10  | -                            | -   | 3                             | 30  | 4                      | 13  |
|                                   |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                                   |          | Severe   | -                            | -   | 1                            | 10  | -                             | -   | 1                      | 3   |
| Erythema/Redness Measurement (mm) | Dose 1   | None     | 10                           | 100 | 10                           | 100 | 10                            | 100 | 30                     | 100 |
|                                   |          | Mild     | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                                   |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                                   |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                                   | Dose 2   | None     | 9                            | 90  | 9                            | 90  | 8                             | 89  | 26                     | 90  |
|                                   |          | Mild     | -                            | -   | -                            | -   | 1                             | 11  | 1                      | 3   |
|                                   |          | Moderate | 1                            | 10  | -                            | -   | -                             | -   | 1                      | 3   |
|                                   |          | Severe   | -                            | -   | 1                            | 10  | -                             | -   | 1                      | 3   |
|                                   | Any Dose | None     | 9                            | 90  | 9                            | 90  | 9                             | 90  | 27                     | 90  |
|                                   |          | Mild     | -                            | -   | -                            | -   | 1                             | 10  | 1                      | 3   |
|                                   |          | Moderate | 1                            | 10  | -                            | -   | -                             | -   | 1                      | 3   |
|                                   |          | Severe   | -                            | -   | 1                            | 10  | -                             | -   | 1                      | 3   |
| Induration/Swelling               | Dose 1   | None     | 8                            | 80  | 8                            | 80  | 7                             | 70  | 23                     | 77  |
|                                   |          | Mild     | 2                            | 20  | -                            | -   | 3                             | 30  | 5                      | 17  |
|                                   |          | Moderate | -                            | -   | 2                            | 20  | -                             | -   | 2                      | 7   |
|                                   |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |

**TABLE 5B(iii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Local Symptoms - 56-70 Years of Age** *(continued)*

|                          |          |          | 25 µg<br>mRNA-1273<br>(N=10) |    | 50 µg<br>mRNA-1273<br>(N=10) |    | 100 µg<br>mRNA-1273<br>(N=10) |     | All Subjects<br>(N=30) |    |
|--------------------------|----------|----------|------------------------------|----|------------------------------|----|-------------------------------|-----|------------------------|----|
| Symptom                  | Dose     | Severity | n                            | %  | n                            | %  | n                             | %   | n                      | %  |
|                          | Dose 2   | None     | 6                            | 60 | 9                            | 90 | 7                             | 78  | 22                     | 76 |
|                          |          | Mild     | 4                            | 40 | -                            | -  | 1                             | 11  | 5                      | 17 |
|                          |          | Moderate | -                            | -  | 1                            | 10 | 1                             | 11  | 2                      | 7  |
|                          |          | Severe   | -                            | -  | -                            | -  | -                             | -   | -                      | -  |
|                          | Any Dose | None     | 5                            | 50 | 7                            | 70 | 7                             | 70  | 19                     | 63 |
|                          |          | Mild     | 5                            | 50 | -                            | -  | 2                             | 20  | 7                      | 23 |
|                          |          | Moderate | -                            | -  | 3                            | 30 | 1                             | 10  | 4                      | 13 |
|                          |          | Severe   | -                            | -  | -                            | -  | -                             | -   | -                      | -  |
| Induration/Swelling (mm) | Dose 1   | None     | 9                            | 90 | 8                            | 80 | 10                            | 100 | 27                     | 90 |
|                          |          | Mild     | 1                            | 10 | -                            | -  | -                             | -   | 1                      | 3  |
|                          |          | Moderate | -                            | -  | 2                            | 20 | -                             | -   | 2                      | 7  |
|                          |          | Severe   | -                            | -  | -                            | -  | -                             | -   | -                      | -  |
|                          | Dose 2   | None     | 8                            | 80 | 9                            | 90 | 8                             | 89  | 25                     | 86 |
|                          |          | Mild     | -                            | -  | -                            | -  | -                             | -   | -                      | -  |
|                          |          | Moderate | 2                            | 20 | 1                            | 10 | 1                             | 11  | 4                      | 14 |
|                          |          | Severe   | -                            | -  | -                            | -  | -                             | -   | -                      | -  |
|                          | Any Dose | None     | 7                            | 70 | 7                            | 70 | 9                             | 90  | 23                     | 77 |
|                          |          | Mild     | 1                            | 10 | -                            | -  | -                             | -   | 1                      | 3  |
|                          |          | Moderate | 2                            | 20 | 3                            | 30 | 1                             | 10  | 6                      | 20 |
|                          |          | Severe   | -                            | -  | -                            | -  | -                             | -   | -                      | -  |

**TABLE 5B(iii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Local Symptoms - 56-70 Years of Age** *(continued)*

|         |          |          | 25 µg<br>mRNA-1273<br>(N=10) |    | 50 µg<br>mRNA-1273<br>(N=10) |    | 100 µg<br>mRNA-1273<br>(N=10) |    | All Subjects<br>(N=30) |    |
|---------|----------|----------|------------------------------|----|------------------------------|----|-------------------------------|----|------------------------|----|
| Symptom | Dose     | Severity | n                            | %  | n                            | %  | n                             | %  | n                      | %  |
| Pain    | Dose 1   | None     | 7                            | 70 | 4                            | 40 | 2                             | 20 | 13                     | 43 |
|         |          | Mild     | 3                            | 30 | 6                            | 60 | 8                             | 80 | 17                     | 57 |
|         |          | Moderate | -                            | -  | -                            | -  | -                             | -  | -                      | -  |
|         |          | Severe   | -                            | -  | -                            | -  | -                             | -  | -                      | -  |
|         | Dose 2   | None     | 5                            | 50 | 2                            | 20 | 1                             | 11 | 8                      | 28 |
|         |          | Mild     | 5                            | 50 | 7                            | 70 | 6                             | 67 | 18                     | 62 |
|         |          | Moderate | -                            | -  | 1                            | 10 | 2                             | 22 | 3                      | 10 |
|         |          | Severe   | -                            | -  | -                            | -  | -                             | -  | -                      | -  |
|         | Any Dose | None     | 4                            | 40 | 1                            | 10 | 1                             | 10 | 6                      | 20 |
|         |          | Mild     | 6                            | 60 | 8                            | 80 | 7                             | 70 | 21                     | 70 |
|         |          | Moderate | -                            | -  | 1                            | 10 | 2                             | 20 | 3                      | 10 |
|         |          | Severe   | -                            | -  | -                            | -  | -                             | -  | -                      | -  |

Severity is the maximum severity reported over all solicited symptoms post dosing for each subject.  
N=All subjects receiving Dose 1 with any solicited event data recorded in the database.

**TABLE 5C(i):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Any Symptom - ≥71 years of Age**

| Symptom     | Dose     | Severity | 25 µg<br>mRNA-1273<br>(N=10) |    | 50 µg<br>mRNA-1273<br>(N=10) |    | 100 µg<br>mRNA-1273<br>(N=10) |    | All Subjects<br>(N=30) |    |
|-------------|----------|----------|------------------------------|----|------------------------------|----|-------------------------------|----|------------------------|----|
|             |          |          | n                            | %  | n                            | %  | n                             | %  | n                      | %  |
| Any Symptom | Dose 1   | None     | 1                            | 10 | 2                            | 20 | 2                             | 20 | 5                      | 17 |
|             |          | Mild     | 9                            | 90 | 7                            | 70 | 8                             | 80 | 24                     | 80 |
|             |          | Moderate | -                            | -  | 1                            | 10 | -                             | -  | 1                      | 3  |
|             |          | Severe   | -                            | -  | -                            | -  | -                             | -  | -                      | -  |
|             | Dose 2   | None     | 1                            | 10 | 3                            | 30 | -                             | -  | 4                      | 13 |
|             |          | Mild     | 7                            | 70 | 6                            | 60 | 5                             | 50 | 18                     | 60 |
|             |          | Moderate | 2                            | 20 | 1                            | 10 | 4                             | 40 | 7                      | 23 |
|             |          | Severe   | -                            | -  | -                            | -  | 1                             | 10 | 1                      | 3  |
|             | Any Dose | None     | -                            | -  | 2                            | 20 | -                             | -  | 2                      | 7  |
|             |          | Mild     | 8                            | 80 | 6                            | 60 | 5                             | 50 | 19                     | 63 |
|             |          | Moderate | 2                            | 20 | 2                            | 20 | 4                             | 40 | 8                      | 27 |
|             |          | Severe   | -                            | -  | -                            | -  | 1                             | 10 | 1                      | 3  |

Severity is the maximum severity reported over all solicited symptoms post dosing for each subject.

N=All subjects receiving Dose 1 with any solicited event data recorded in the database.

**TABLE 5C(ii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Systemic Symptoms - ≥71 years of Age**

|                      |          |          | 25 µg<br>mRNA-1273<br>(N=10) |     | 50 µg<br>mRNA-1273<br>(N=10) |     | 100 µg<br>mRNA-1273<br>(N=10) |     | All Subjects<br>(N=30) |    |
|----------------------|----------|----------|------------------------------|-----|------------------------------|-----|-------------------------------|-----|------------------------|----|
| Symptom              | Dose     | Severity | n                            | %   | n                            | %   | n                             | %   | n                      | %  |
| Any Systemic Symptom | Dose 1   | None     | 5                            | 50  | 6                            | 60  | 7                             | 70  | 18                     | 60 |
|                      |          | Mild     | 5                            | 50  | 3                            | 30  | 3                             | 30  | 11                     | 37 |
|                      |          | Moderate | -                            | -   | 1                            | 10  | -                             | -   | 1                      | 3  |
|                      |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -  |
|                      | Dose 2   | None     | 7                            | 70  | 4                            | 40  | 3                             | 30  | 14                     | 47 |
|                      |          | Mild     | 3                            | 30  | 5                            | 50  | 3                             | 30  | 11                     | 37 |
|                      |          | Moderate | -                            | -   | 1                            | 10  | 3                             | 30  | 4                      | 13 |
|                      |          | Severe   | -                            | -   | -                            | -   | 1                             | 10  | 1                      | 3  |
|                      | Any Dose | None     | 5                            | 50  | 4                            | 40  | 3                             | 30  | 12                     | 40 |
|                      |          | Mild     | 5                            | 50  | 4                            | 40  | 3                             | 30  | 12                     | 40 |
|                      |          | Moderate | -                            | -   | 2                            | 20  | 3                             | 30  | 5                      | 17 |
|                      |          | Severe   | -                            | -   | -                            | -   | 1                             | 10  | 1                      | 3  |
| Arthralgia           | Dose 1   | None     | 9                            | 90  | 9                            | 90  | 10                            | 100 | 28                     | 93 |
|                      |          | Mild     | 1                            | 10  | 1                            | 10  | -                             | -   | 2                      | 7  |
|                      |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -  |
|                      |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -  |
|                      | Dose 2   | None     | 10                           | 100 | 10                           | 100 | 8                             | 80  | 28                     | 93 |
|                      |          | Mild     | -                            | -   | -                            | -   | 2                             | 20  | 2                      | 7  |
|                      |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -  |
|                      |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -  |



**TABLE 5C(ii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Systemic Symptoms - ≥71 years of Age** *(continued)*

|                    |          |          | 25 µg<br>mRNA-1273<br>(N=10) |     | 50 µg<br>mRNA-1273<br>(N=10) |     | 100 µg<br>mRNA-1273<br>(N=10) |     | All Subjects<br>(N=30) |     |
|--------------------|----------|----------|------------------------------|-----|------------------------------|-----|-------------------------------|-----|------------------------|-----|
| Symptom            | Dose     | Severity | n                            | %   | n                            | %   | n                             | %   | n                      | %   |
| Fatigue            | Any Dose | None     | 9                            | 90  | 9                            | 90  | 8                             | 80  | 26                     | 87  |
|                    |          | Mild     | 1                            | 10  | 1                            | 10  | 2                             | 20  | 4                      | 13  |
|                    |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                    |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                    | Dose 1   | None     | 8                            | 80  | 6                            | 60  | 7                             | 70  | 21                     | 70  |
|                    |          | Mild     | 2                            | 20  | 3                            | 30  | 3                             | 30  | 8                      | 27  |
|                    |          | Moderate | -                            | -   | 1                            | 10  | -                             | -   | 1                      | 3   |
|                    |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                    | Dose 2   | None     | 9                            | 90  | 5                            | 50  | 3                             | 30  | 17                     | 57  |
|                    |          | Mild     | 1                            | 10  | 4                            | 40  | 3                             | 30  | 8                      | 27  |
|                    |          | Moderate | -                            | -   | 1                            | 10  | 3                             | 30  | 4                      | 13  |
|                    |          | Severe   | -                            | -   | -                            | -   | 1                             | 10  | 1                      | 3   |
|                    | Any Dose | None     | 7                            | 70  | 5                            | 50  | 3                             | 30  | 15                     | 50  |
|                    |          | Mild     | 3                            | 30  | 3                            | 30  | 3                             | 30  | 9                      | 30  |
|                    |          | Moderate | -                            | -   | 2                            | 20  | 3                             | 30  | 5                      | 17  |
|                    |          | Severe   | -                            | -   | -                            | -   | 1                             | 10  | 1                      | 3   |
| Fever <sup>a</sup> | Dose 1   | None     | 10                           | 100 | 10                           | 100 | 10                            | 100 | 30                     | 100 |
|                    |          | Mild     | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                    |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                    |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |

**TABLE 5C(ii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Systemic Symptoms -  $\geq 71$  years of Age** *(continued)*

|              |          |          | 25 µg<br>mRNA-1273<br>(N=10) |     | 50 µg<br>mRNA-1273<br>(N=10) |     | 100 µg<br>mRNA-1273<br>(N=10) |    | All Subjects<br>(N=30) |    |
|--------------|----------|----------|------------------------------|-----|------------------------------|-----|-------------------------------|----|------------------------|----|
| Symptom      | Dose     | Severity | n                            | %   | n                            | %   | n                             | %  | n                      | %  |
|              | Dose 2   | None     | 10                           | 100 | 10                           | 100 | 9                             | 90 | 29                     | 97 |
|              |          | Mild     | -                            | -   | -                            | -   | 1                             | 10 | 1                      | 3  |
|              |          | Moderate | -                            | -   | -                            | -   | -                             | -  | -                      | -  |
|              |          | Severe   | -                            | -   | -                            | -   | -                             | -  | -                      | -  |
|              | Any Dose | None     | 10                           | 100 | 10                           | 100 | 9                             | 90 | 29                     | 97 |
|              |          | Mild     | -                            | -   | -                            | -   | 1                             | 10 | 1                      | 3  |
|              |          | Moderate | -                            | -   | -                            | -   | -                             | -  | -                      | -  |
|              |          | Severe   | -                            | -   | -                            | -   | -                             | -  | -                      | -  |
| Feverishness | Dose 1   | None     | 10                           | 100 | 10                           | 100 | 9                             | 90 | 29                     | 97 |
|              |          | Mild     | -                            | -   | -                            | -   | 1                             | 10 | 1                      | 3  |
|              |          | Moderate | -                            | -   | -                            | -   | -                             | -  | -                      | -  |
|              |          | Severe   | -                            | -   | -                            | -   | -                             | -  | -                      | -  |
|              | Dose 2   | None     | 10                           | 100 | 10                           | 100 | 6                             | 60 | 26                     | 87 |
|              |          | Mild     | -                            | -   | -                            | -   | 3                             | 30 | 3                      | 10 |
|              |          | Moderate | -                            | -   | -                            | -   | 1                             | 10 | 1                      | 3  |
|              |          | Severe   | -                            | -   | -                            | -   | -                             | -  | -                      | -  |
|              | Any Dose | None     | 10                           | 100 | 10                           | 100 | 5                             | 50 | 25                     | 83 |
|              |          | Mild     | -                            | -   | -                            | -   | 4                             | 40 | 4                      | 13 |
|              |          | Moderate | -                            | -   | -                            | -   | 1                             | 10 | 1                      | 3  |
|              |          | Severe   | -                            | -   | -                            | -   | -                             | -  | -                      | -  |

**TABLE 5C(ii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Systemic Symptoms -  $\geq 71$  years of Age** *(continued)*

| Symptom  | Dose     | Severity | 25 µg<br>mRNA-1273<br>(N=10) |    | 50 µg<br>mRNA-1273<br>(N=10) |     | 100 µg<br>mRNA-1273<br>(N=10) |     | All Subjects<br>(N=30) |    |
|----------|----------|----------|------------------------------|----|------------------------------|-----|-------------------------------|-----|------------------------|----|
|          |          |          | n                            | %  | n                            | %   | n                             | %   | n                      | %  |
| Headache | Dose 1   | None     | 7                            | 70 | 9                            | 90  | 10                            | 100 | 26                     | 87 |
|          |          | Mild     | 3                            | 30 | 1                            | 10  | -                             | -   | 4                      | 13 |
|          |          | Moderate | -                            | -  | -                            | -   | -                             | -   | -                      | -  |
|          |          | Severe   | -                            | -  | -                            | -   | -                             | -   | -                      | -  |
|          | Dose 2   | None     | 8                            | 80 | 10                           | 100 | 6                             | 60  | 24                     | 80 |
|          |          | Mild     | 2                            | 20 | -                            | -   | 3                             | 30  | 5                      | 17 |
|          |          | Moderate | -                            | -  | -                            | -   | 1                             | 10  | 1                      | 3  |
|          |          | Severe   | -                            | -  | -                            | -   | -                             | -   | -                      | -  |
|          | Any Dose | None     | 6                            | 60 | 9                            | 90  | 6                             | 60  | 21                     | 70 |
|          |          | Mild     | 4                            | 40 | 1                            | 10  | 3                             | 30  | 8                      | 27 |
|          |          | Moderate | -                            | -  | -                            | -   | 1                             | 10  | 1                      | 3  |
|          |          | Severe   | -                            | -  | -                            | -   | -                             | -   | -                      | -  |
| Myalgia  | Dose 1   | None     | 7                            | 70 | 10                           | 100 | 8                             | 80  | 25                     | 83 |
|          |          | Mild     | 3                            | 30 | -                            | -   | 2                             | 20  | 5                      | 17 |
|          |          | Moderate | -                            | -  | -                            | -   | -                             | -   | -                      | -  |
|          |          | Severe   | -                            | -  | -                            | -   | -                             | -   | -                      | -  |
|          | Dose 2   | None     | 9                            | 90 | 8                            | 80  | 4                             | 40  | 21                     | 70 |
|          |          | Mild     | 1                            | 10 | 2                            | 20  | 5                             | 50  | 8                      | 27 |
|          |          | Moderate | -                            | -  | -                            | -   | 1                             | 10  | 1                      | 3  |
|          |          | Severe   | -                            | -  | -                            | -   | -                             | -   | -                      | -  |

**TABLE 5C(ii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and Vaccination Group – Systemic Symptoms -  $\geq 71$  years of Age** *(continued)*

| Symptom | Dose     | Severity | 25 µg<br>mRNA-1273<br>(N=10) |     | 50 µg<br>mRNA-1273<br>(N=10) |     | 100 µg<br>mRNA-1273<br>(N=10) |     | All Subjects<br>(N=30) |     |
|---------|----------|----------|------------------------------|-----|------------------------------|-----|-------------------------------|-----|------------------------|-----|
|         |          |          | n                            | %   | n                            | %   | n                             | %   | n                      | %   |
|         | Any Dose | None     | 7                            | 70  | 8                            | 80  | 4                             | 40  | 19                     | 63  |
|         |          | Mild     | 3                            | 30  | 2                            | 20  | 5                             | 50  | 10                     | 33  |
|         |          | Moderate | -                            | -   | -                            | -   | 1                             | 10  | 1                      | 3   |
|         |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
| Nausea  | Dose 1   | None     | 10                           | 100 | 10                           | 100 | 10                            | 100 | 30                     | 100 |
|         |          | Mild     | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|         |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|         |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|         | Dose 2   | None     | 10                           | 100 | 10                           | 100 | 9                             | 90  | 29                     | 97  |
|         |          | Mild     | -                            | -   | -                            | -   | 1                             | 10  | 1                      | 3   |
|         |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|         |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|         | Any Dose | None     | 10                           | 100 | 10                           | 100 | 9                             | 90  | 29                     | 97  |
|         |          | Mild     | -                            | -   | -                            | -   | 1                             | 10  | 1                      | 3   |
|         |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|         |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |

Severity is the maximum severity reported over all solicited symptoms post dosing for each subject.

N=All subjects receiving Dose 1 with any solicited event data recorded in the database.

\*Fever percentages reflect the number of subjects with at least one measurement available in the data system as the denominator. This denominator may differ from other systemic symptoms, which are solicited in-clinic at the post-dose assessment.

**TABLE 5C(iii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Local Symptoms - ≥71 years of Age**

|                   |          |          | 25 µg<br>mRNA-1273<br>(N=10) |    | 50 µg<br>mRNA-1273<br>(N=10) |     | 100 µg<br>mRNA-1273<br>(N=10) |     | All Subjects<br>(N=30) |    |
|-------------------|----------|----------|------------------------------|----|------------------------------|-----|-------------------------------|-----|------------------------|----|
| Symptom           | Dose     | Severity | n                            | %  | n                            | %   | n                             | %   | n                      | %  |
| Any Local Symptom | Dose 1   | None     | 4                            | 40 | 3                            | 30  | 2                             | 20  | 9                      | 30 |
|                   |          | Mild     | 6                            | 60 | 7                            | 70  | 8                             | 80  | 21                     | 70 |
|                   |          | Moderate | -                            | -  | -                            | -   | -                             | -   | -                      | -  |
|                   |          | Severe   | -                            | -  | -                            | -   | -                             | -   | -                      | -  |
|                   | Dose 2   | None     | 3                            | 30 | 6                            | 60  | -                             | -   | 9                      | 30 |
|                   |          | Mild     | 5                            | 50 | 4                            | 40  | 6                             | 60  | 15                     | 50 |
|                   |          | Moderate | 2                            | 20 | -                            | -   | 4                             | 40  | 6                      | 20 |
|                   |          | Severe   | -                            | -  | -                            | -   | -                             | -   | -                      | -  |
|                   | Any Dose | None     | 2                            | 20 | 3                            | 30  | -                             | -   | 5                      | 17 |
|                   |          | Mild     | 6                            | 60 | 7                            | 70  | 6                             | 60  | 19                     | 63 |
|                   |          | Moderate | 2                            | 20 | -                            | -   | 4                             | 40  | 6                      | 20 |
|                   |          | Severe   | -                            | -  | -                            | -   | -                             | -   | -                      | -  |
| Erythema/Redness  | Dose 1   | None     | 9                            | 90 | 9                            | 90  | 10                            | 100 | 28                     | 93 |
|                   |          | Mild     | 1                            | 10 | 1                            | 10  | -                             | -   | 2                      | 7  |
|                   |          | Moderate | -                            | -  | -                            | -   | -                             | -   | -                      | -  |
|                   |          | Severe   | -                            | -  | -                            | -   | -                             | -   | -                      | -  |
|                   | Dose 2   | None     | 7                            | 70 | 10                           | 100 | 6                             | 60  | 23                     | 77 |
|                   |          | Mild     | 3                            | 30 | -                            | -   | 4                             | 40  | 7                      | 23 |
|                   |          | Moderate | -                            | -  | -                            | -   | -                             | -   | -                      | -  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 5C(iii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Local Symptoms - ≥71 years of Age (continued)**

|                                   |          |          | 25 µg<br>mRNA-1273<br>(N=10) |     | 50 µg<br>mRNA-1273<br>(N=10) |     | 100 µg<br>mRNA-1273<br>(N=10) |     | All Subjects<br>(N=30) |     |
|-----------------------------------|----------|----------|------------------------------|-----|------------------------------|-----|-------------------------------|-----|------------------------|-----|
| Symptom                           | Dose     | Severity | n                            | %   | n                            | %   | n                             | %   | n                      | %   |
|                                   | Any Dose | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                                   |          | None     | 7                            | 70  | 9                            | 90  | 6                             | 60  | 22                     | 73  |
|                                   |          | Mild     | 3                            | 30  | 1                            | 10  | 4                             | 40  | 8                      | 27  |
|                                   |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                                   |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
| Erythema/Redness Measurement (mm) | Dose 1   | None     | 10                           | 100 | 10                           | 100 | 10                            | 100 | 30                     | 100 |
|                                   |          | Mild     | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                                   |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                                   |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                                   | Dose 2   | None     | 8                            | 80  | 10                           | 100 | 8                             | 80  | 26                     | 87  |
|                                   |          | Mild     | -                            | -   | -                            | -   | 1                             | 10  | 1                      | 3   |
|                                   |          | Moderate | 2                            | 20  | -                            | -   | 1                             | 10  | 3                      | 10  |
|                                   |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                                   | Any Dose | None     | 8                            | 80  | 10                           | 100 | 8                             | 80  | 26                     | 87  |
|                                   |          | Mild     | -                            | -   | -                            | -   | 1                             | 10  | 1                      | 3   |
|                                   |          | Moderate | 2                            | 20  | -                            | -   | 1                             | 10  | 3                      | 10  |
|                                   |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
| Induration/Swelling               | Dose 1   | None     | 10                           | 100 | 8                            | 80  | 10                            | 100 | 28                     | 93  |
|                                   |          | Mild     | -                            | -   | 2                            | 20  | -                             | -   | 2                      | 7   |
|                                   |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -   |
|                                   |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 5C(iii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Local Symptoms - ≥71 years of Age (continued)**

|                          |          |          | 25 µg<br>mRNA-1273<br>(N=10) |     | 50 µg<br>mRNA-1273<br>(N=10) |     | 100 µg<br>mRNA-1273<br>(N=10) |     | All Subjects<br>(N=30) |    |
|--------------------------|----------|----------|------------------------------|-----|------------------------------|-----|-------------------------------|-----|------------------------|----|
| Symptom                  | Dose     | Severity | n                            | %   | n                            | %   | n                             | %   | n                      | %  |
|                          | Dose 2   | None     | 8                            | 80  | 10                           | 100 | 7                             | 70  | 25                     | 83 |
|                          |          | Mild     | 2                            | 20  | -                            | -   | 3                             | 30  | 5                      | 17 |
|                          |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -  |
|                          |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -  |
|                          | Any Dose | None     | 8                            | 80  | 8                            | 80  | 7                             | 70  | 23                     | 77 |
|                          |          | Mild     | 2                            | 20  | 2                            | 20  | 3                             | 30  | 7                      | 23 |
|                          |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -  |
|                          |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -  |
| Induration/Swelling (mm) | Dose 1   | None     | 10                           | 100 | 9                            | 90  | 10                            | 100 | 29                     | 97 |
|                          |          | Mild     | -                            | -   | 1                            | 10  | -                             | -   | 1                      | 3  |
|                          |          | Moderate | -                            | -   | -                            | -   | -                             | -   | -                      | -  |
|                          |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -  |
|                          | Dose 2   | None     | 8                            | 80  | 10                           | 100 | 7                             | 70  | 25                     | 83 |
|                          |          | Mild     | -                            | -   | -                            | -   | -                             | -   | -                      | -  |
|                          |          | Moderate | 2                            | 20  | -                            | -   | 3                             | 30  | 5                      | 17 |
|                          |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -  |
|                          | Any Dose | None     | 8                            | 80  | 9                            | 90  | 7                             | 70  | 24                     | 80 |
|                          |          | Mild     | -                            | -   | 1                            | 10  | -                             | -   | 1                      | 3  |
|                          |          | Moderate | 2                            | 20  | -                            | -   | 3                             | 30  | 5                      | 17 |
|                          |          | Severe   | -                            | -   | -                            | -   | -                             | -   | -                      | -  |
| Pain                     | Dose 1   | None     | 4                            | 40  | 3                            | 30  | 2                             | 20  | 9                      | 30 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 5C(iii):**  
**Number and Percentage of Subjects Experiencing Solicited Events by Symptom, Maximum Severity, Dose, and**  
**Vaccination Group – Local Symptoms - ≥71 years of Age (continued)**

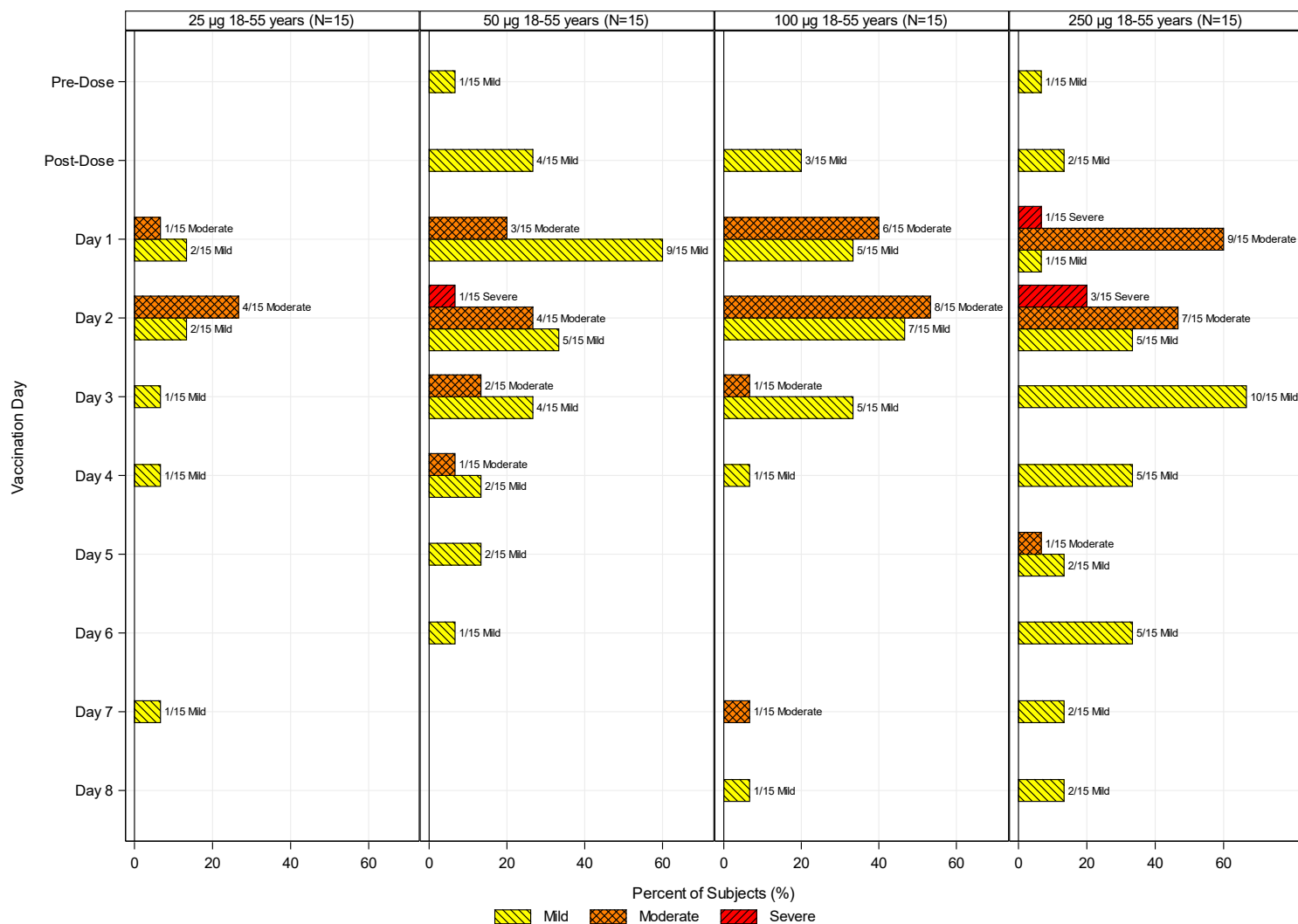
|         |          |          | 25 µg<br>mRNA-1273<br>(N=10) |    | 50 µg<br>mRNA-1273<br>(N=10) |    | 100 µg<br>mRNA-1273<br>(N=10) |    | All Subjects<br>(N=30) |    |
|---------|----------|----------|------------------------------|----|------------------------------|----|-------------------------------|----|------------------------|----|
| Symptom | Dose     | Severity | n                            | %  | n                            | %  | n                             | %  | n                      | %  |
|         |          | Mild     | 6                            | 60 | 7                            | 70 | 8                             | 80 | 21                     | 70 |
|         |          | Moderate | -                            | -  | -                            | -  | -                             | -  | -                      | -  |
|         |          | Severe   | -                            | -  | -                            | -  | -                             | -  | -                      | -  |
|         | Dose 2   | None     | 4                            | 40 | 6                            | 60 | -                             | -  | 10                     | 33 |
|         |          | Mild     | 6                            | 60 | 4                            | 40 | 9                             | 90 | 19                     | 63 |
|         |          | Moderate | -                            | -  | -                            | -  | 1                             | 10 | 1                      | 3  |
|         |          | Severe   | -                            | -  | -                            | -  | -                             | -  | -                      | -  |
|         | Any Dose | None     | 2                            | 20 | 3                            | 30 | -                             | -  | 5                      | 17 |
|         |          | Mild     | 8                            | 80 | 7                            | 70 | 9                             | 90 | 24                     | 80 |
|         |          | Moderate | -                            | -  | -                            | -  | 1                             | 10 | 1                      | 3  |
|         |          | Severe   | -                            | -  | -                            | -  | -                             | -  | -                      | -  |

Severity is the maximum severity reported over all solicited symptoms post dosing for each subject.

N=All subjects receiving Dose 1 with any solicited event data recorded in the database.

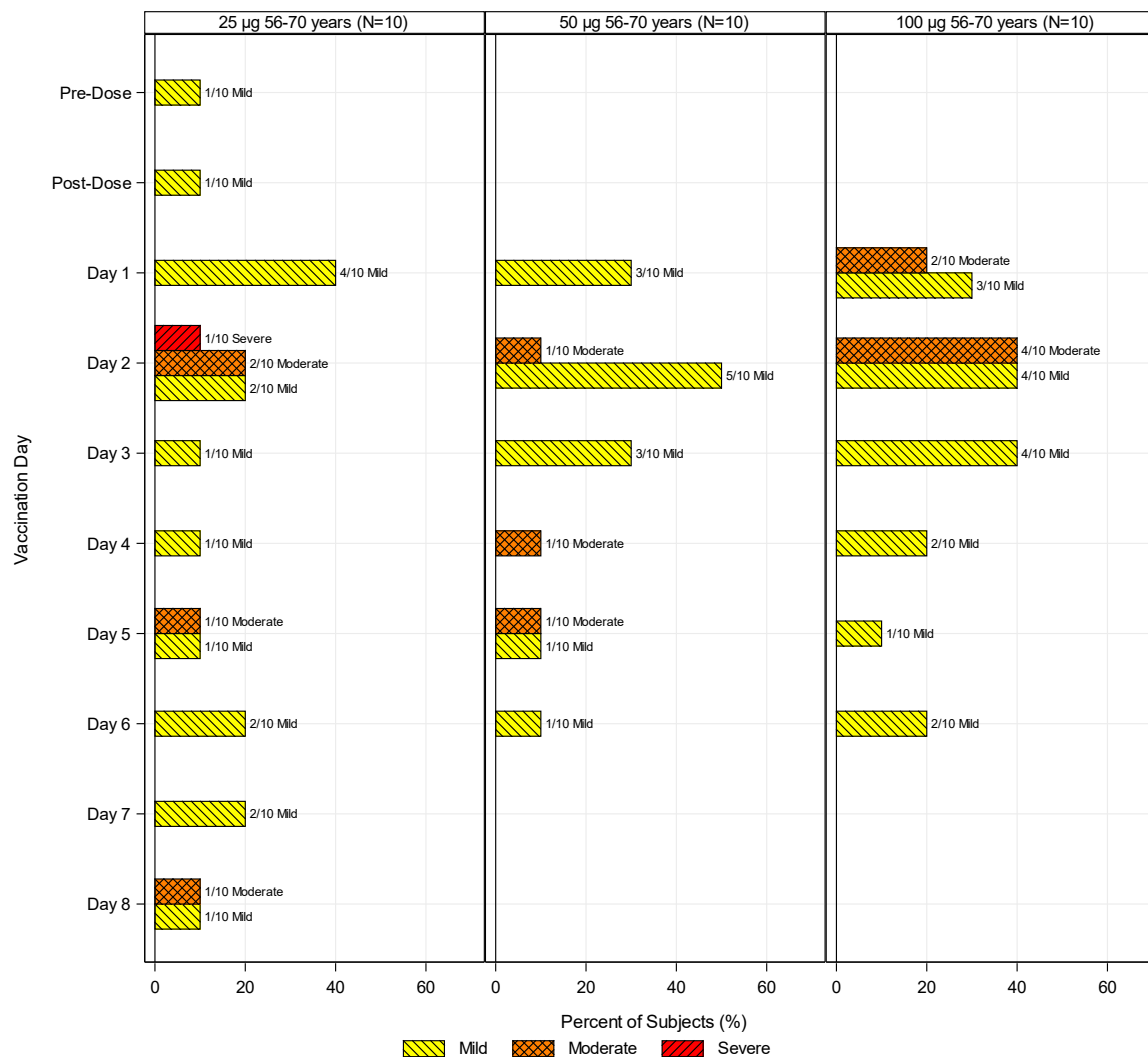


**FIGURE 2A(i):  
Maximum Severity of Solicited Systemic Symptoms by Days Post Vaccination and Vaccination Group - 18-55 Years of Age**



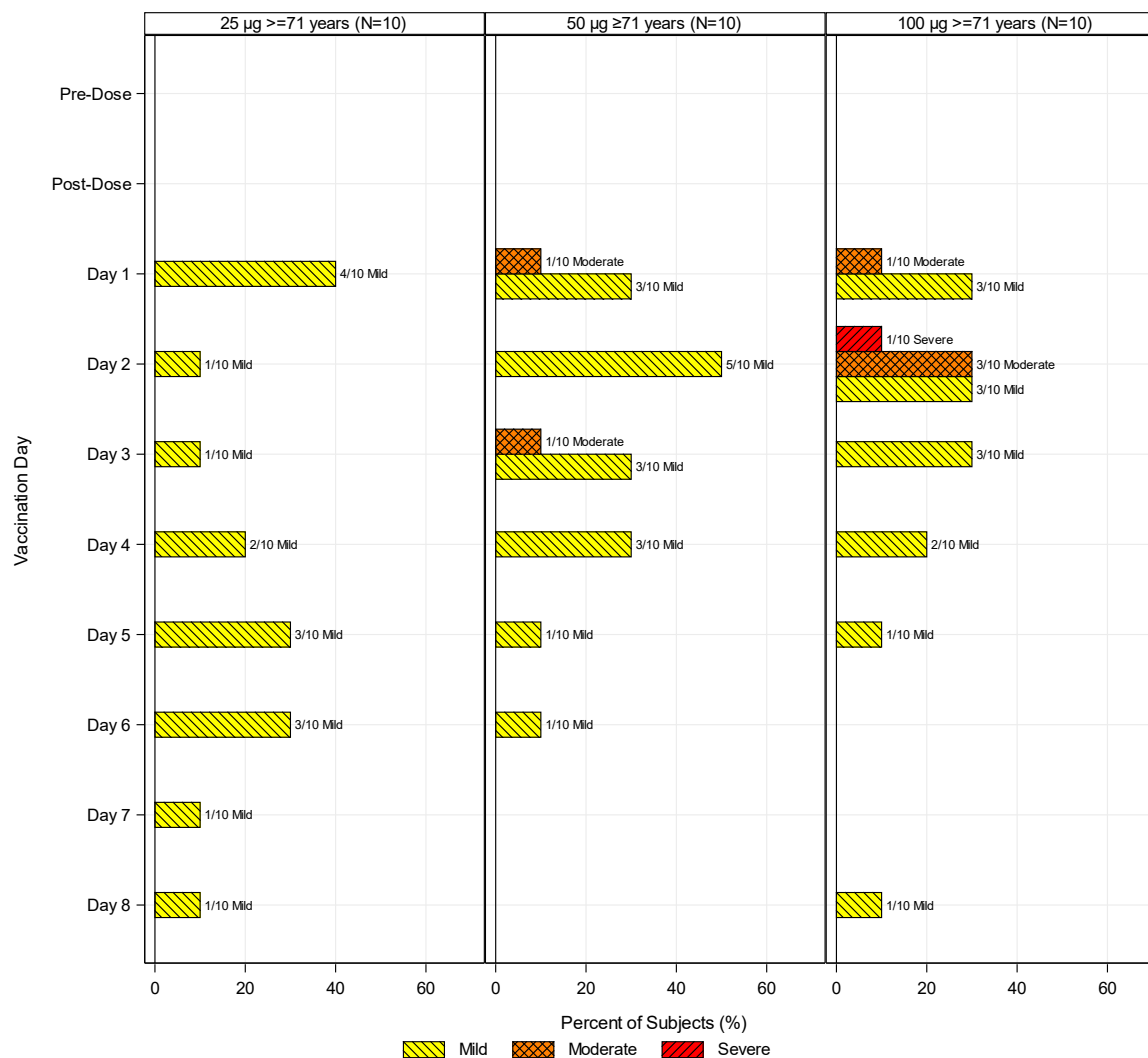
Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 2A(ii):  
Maximum Severity of Solicited Systemic Symptoms by Days Post Vaccination and Vaccination Group – 56-70 Years of Age**



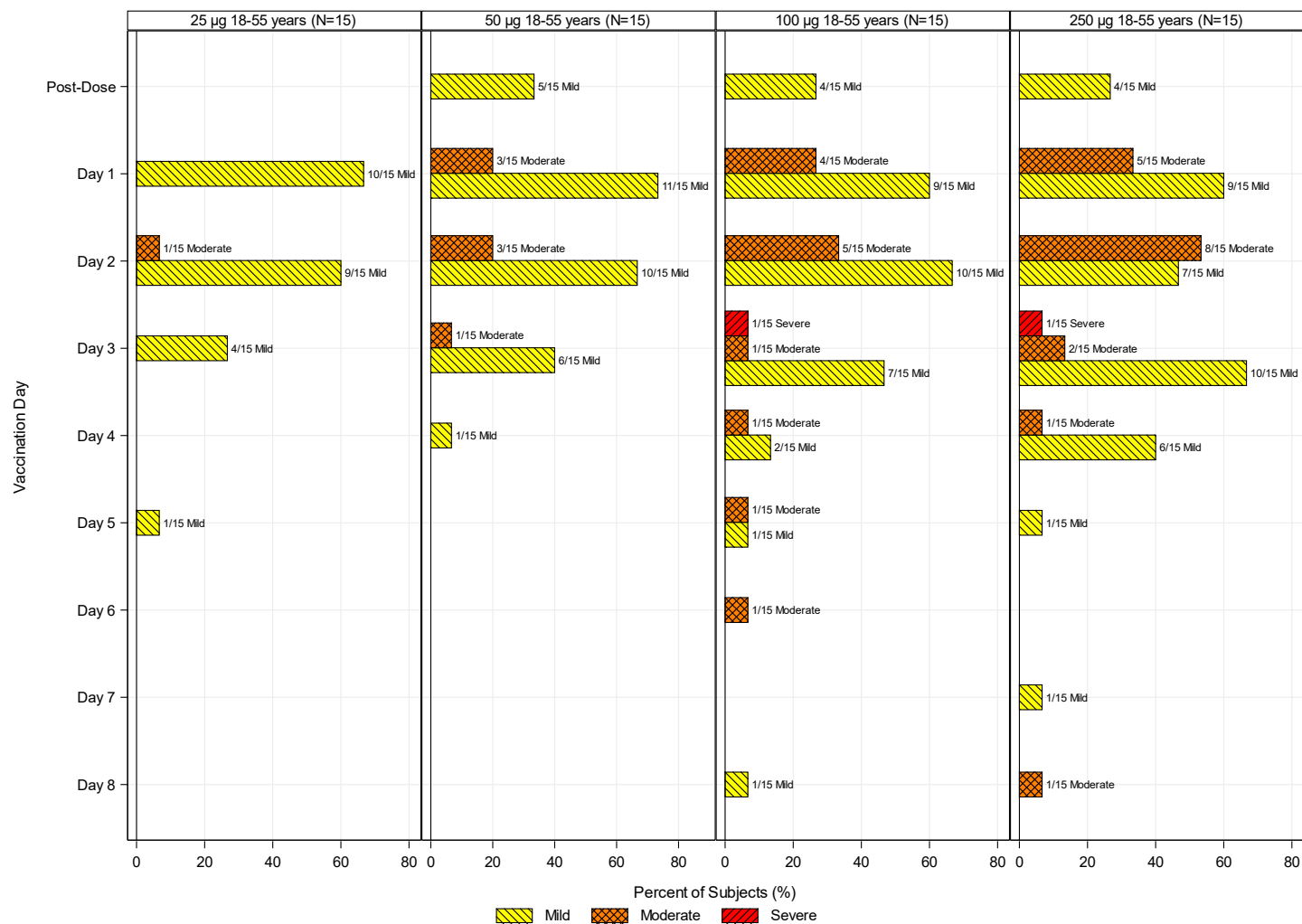
Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 2A(iii):**  
**Maximum Severity of Solicited Systemic Symptoms by Days Post Vaccination and Vaccination Group -  $\geq 71$  Years of Age**



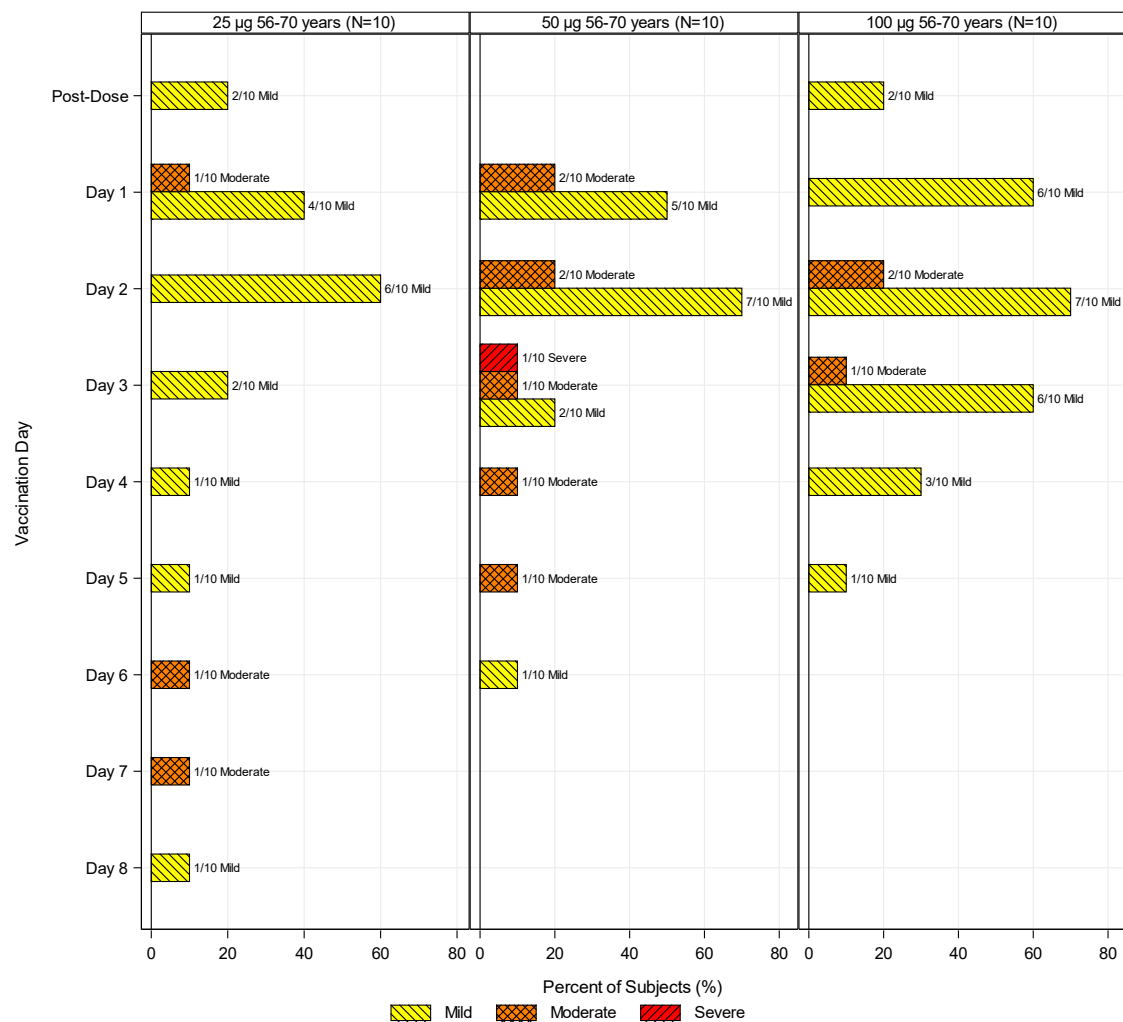
Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 3A(i):  
Maximum Severity of Solicited Local Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age**

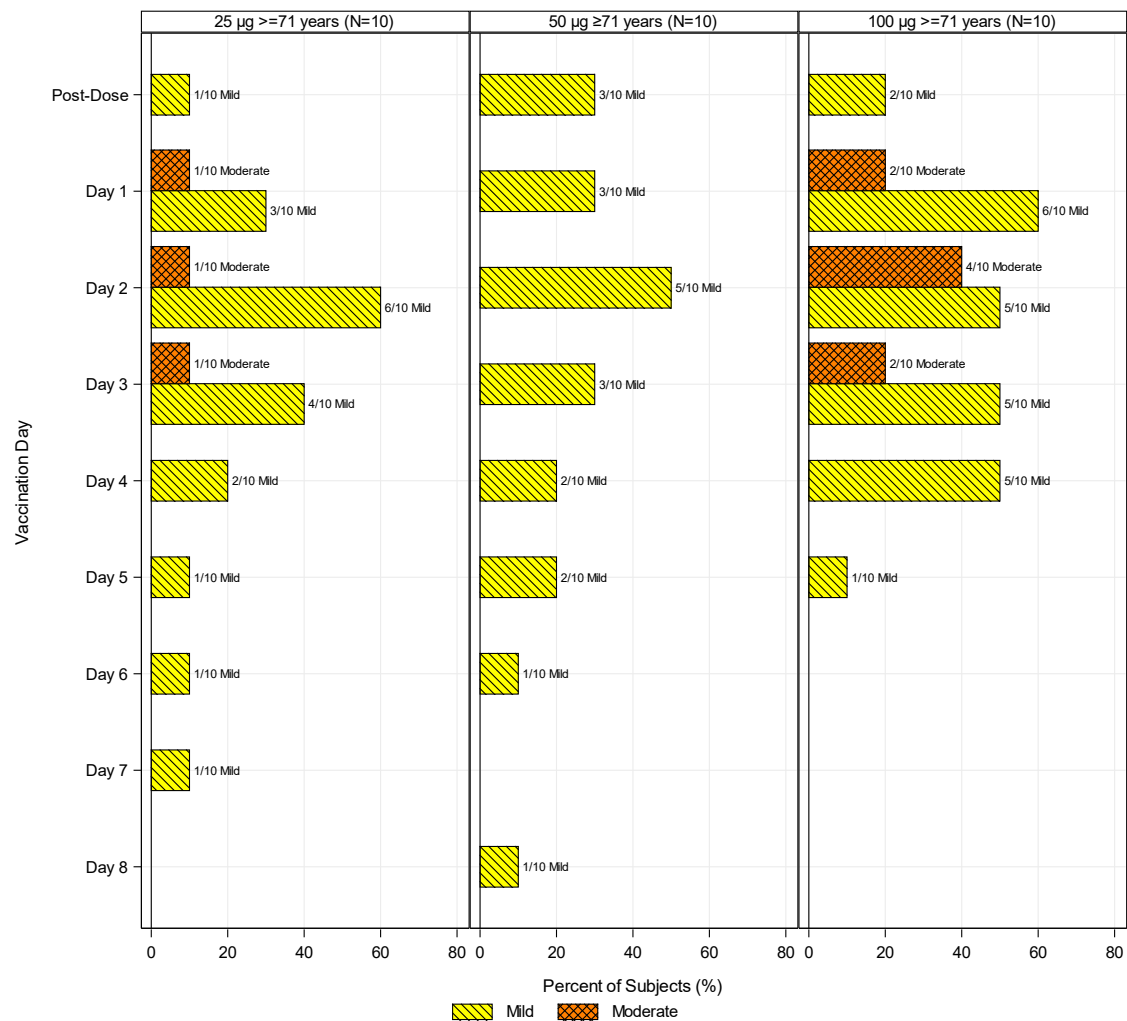


Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 3A(ii):**  
**Maximum Severity of Solicited Local Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age**



**FIGURE 3A(iii):**  
**Maximum Severity of Solicited Local Symptoms by Days Post Vaccination and Vaccination Group  $\geq 71$  Years of Age**



**FIGURE 4A(i):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age -  
Arthralgia**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4A(ii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age -  
Arthralgia**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**FIGURE 4A(iii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group  $\geq 71$  Years of Age –  
Arthralgia**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4B(i):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age - Chills**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4B(ii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age - Chills**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4B(iii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group  $\geq 71$  Years of Age – Chills**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4C(i):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age -  
Erythema**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4C(ii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age -  
Erythema**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4C(iii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group  $\geq 71$  Years of Age –  
Erythema**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4D(i):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age –  
Erythema (mm)**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**FIGURE 4D(ii):**  
**Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age – Erythema (mm)**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4D(iii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group  $\geq 71$  Years of Age –  
Erythema (mm)**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4E(i):**

**Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age - Fatigue**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4E(ii):**

**Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age - Fatigue**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4E(iii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group  $\geq 71$  Years of Age – Fatigue**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4F(i):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age - Fever**



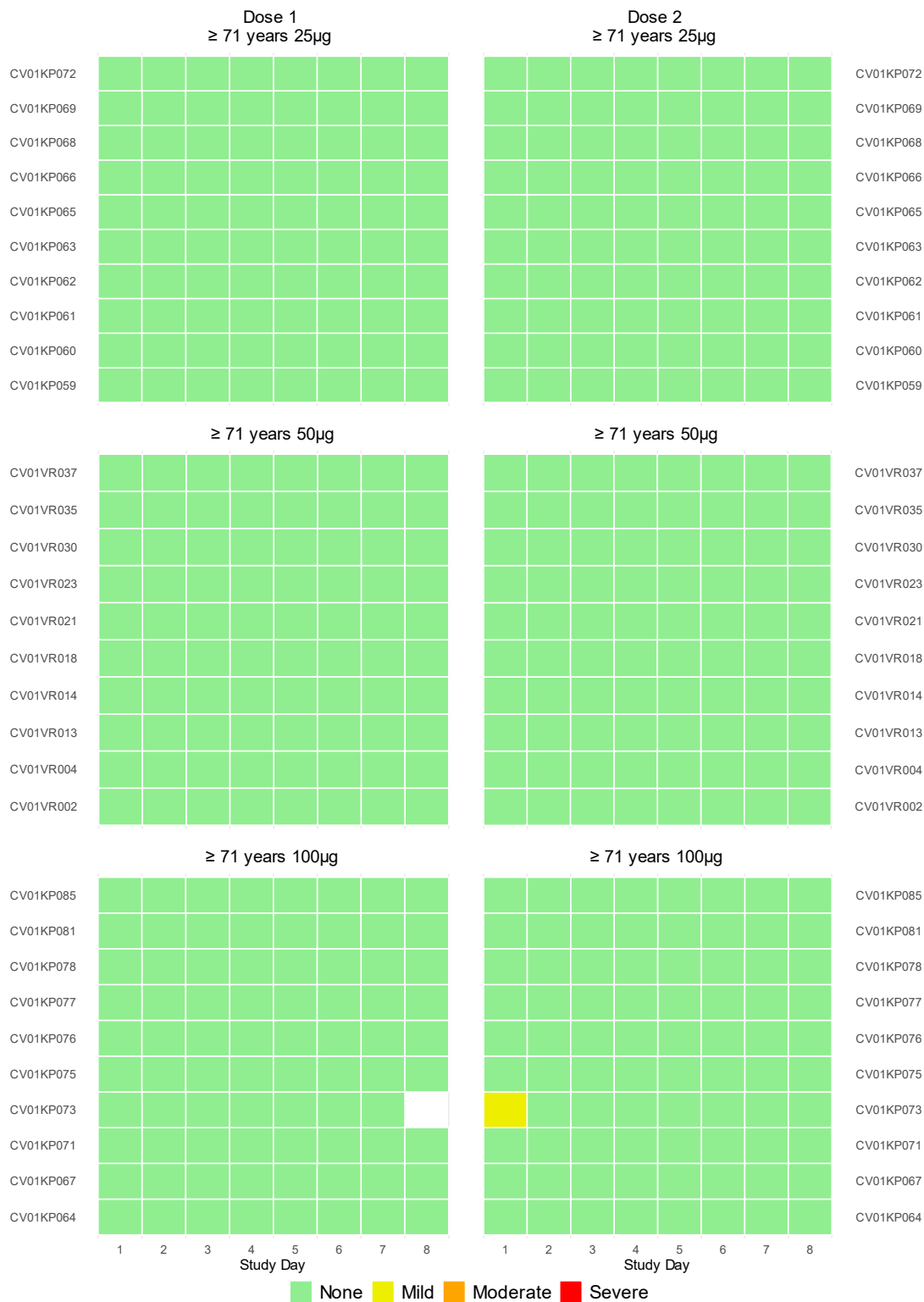
Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4F(ii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age - Fever**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4F(iii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group  $\geq 71$  Years of Age – Fever**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**FIGURE 4G(i):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age -  
Headache**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4G(ii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age -  
Headache**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4G(iii):**

**Solicited Symptoms by Days Post Vaccination and Vaccination Group  $\geq 71$  Years of Age – Headache**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4H(i):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age -  
Induration**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4H(ii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age -  
Induration**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4H(iii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group  $\geq 71$  Years of Age –  
Induration**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4I(i):**  
**Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age –**  
**Induration (mm)**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4I(ii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age –  
Induration (mm)**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**FIGURE 4I(iii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group  $\geq 71$  Years of Age –  
Induration (mm)**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4J(i):**

**Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age - Myalgia**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4J(ii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age - Myalgia**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4J(iii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group  $\geq 71$  Years of Age – Myalgia**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4K(i):**  
**Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age - Nausea**



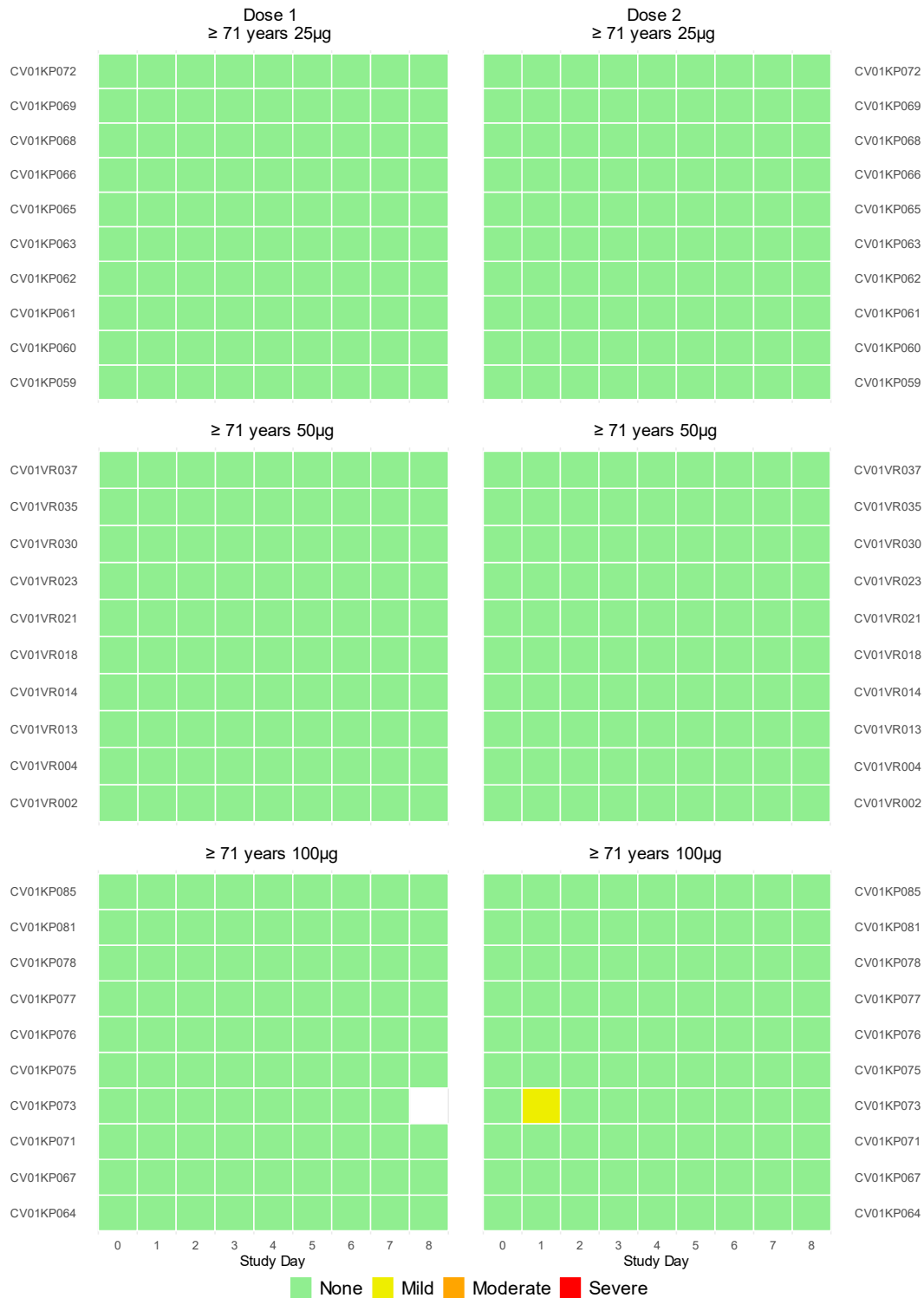
Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4K(ii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age - Nausea**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4K(iii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group  $\geq 71$  Years of Age – Nausea**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4L(i):**  
**Solicited Symptoms by Days Post Vaccination and Vaccination Group 18-55 Years of Age - Pain**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

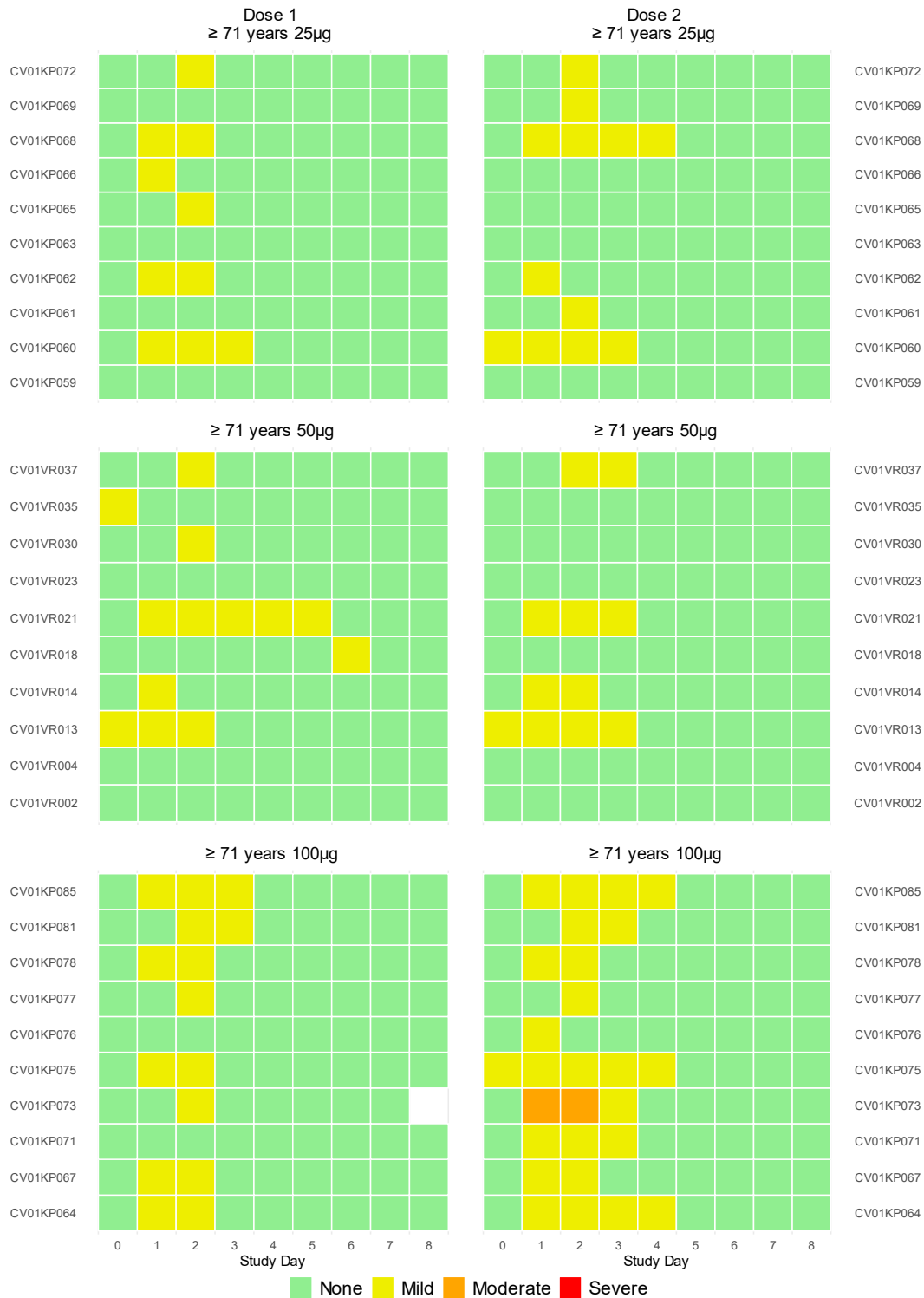


**FIGURE 4L(ii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group 56-70 Years of Age - Pain**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 4L(iii):  
Solicited Symptoms by Days Post Vaccination and Vaccination Group  $\geq 71$  Years of Age – Pain**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 6A:**  
**Summary of Duration of Solicited Symptoms by Vaccination Group - All Subjects 18-55 Years of Age**

|                     |                    | 25 µg<br>mRNA-1273<br>(N=15) |        |     | 50 µg<br>mRNA -1273<br>(N=15) |        |     | 100 µg<br>mRNA -1273<br>(N=15) |        |     | 250 µg<br>mRNA -1273<br>(N=15) |        |     | All Subjects<br>(N=60) |        |     |
|---------------------|--------------------|------------------------------|--------|-----|-------------------------------|--------|-----|--------------------------------|--------|-----|--------------------------------|--------|-----|------------------------|--------|-----|
| Variable            | Statistic          | Dose 1                       | Dose 2 | All | Dose 1                        | Dose 2 | All | Dose 1                         | Dose 2 | All | Dose 1                         | Dose 2 | All | Dose 1                 | Dose 2 | All |
| Any Symptom         | n                  | 21                           | 27     | 48  | 35                            | 52     | 87  | 34                             | 77     | 111 | 47                             | 97     | 144 | 137                    | 253    | 390 |
|                     | Mean               | 1.3                          | 1.5    | 1.4 | 1.9                           | 1.6    | 1.7 | 1.5                            | 1.7    | 1.7 | 2.2                            | 1.9    | 2.0 | 1.8                    | 1.8    | 1.8 |
|                     | Standard Deviation | 0.6                          | 0.8    | 0.7 | 1.1                           | 0.8    | 0.9 | 0.6                            | 1.0    | 0.9 | 1.2                            | 1.0    | 1.1 | 1.0                    | 0.9    | 1.0 |
|                     | Median             | 1.0                          | 1.0    | 1.0 | 2.0                           | 1.0    | 1.0 | 1.5                            | 1.0    | 1.0 | 2.0                            | 2.0    | 2.0 | 2.0                    | 1.0    | 1.0 |
|                     | Minimum            | 1                            | 1      | 1   | 1                             | 1      | 1   | 1                              | 1      | 1   | 1                              | 1      | 1   | 1                      | 1      | 1   |
|                     | Maximum            | 3                            | 3      | 3   | 6                             | 3      | 6   | 3                              | 5      | 5   | 5                              | 6      | 6   | 6                      | 6      | 6   |
| Any Local Symptom   | n                  | 10                           | 12     | 22  | 17                            | 17     | 34  | 22                             | 19     | 41  | 25                             | 22     | 47  | 74                     | 70     | 144 |
|                     | Mean               | 1.7                          | 2.0    | 1.9 | 2.1                           | 1.8    | 1.9 | 1.7                            | 2.7    | 2.1 | 2.3                            | 2.6    | 2.4 | 2.0                    | 2.3    | 2.2 |
|                     | Standard Deviation | 0.7                          | 0.9    | 0.8 | 0.9                           | 0.8    | 0.9 | 0.6                            | 1.2    | 1.1 | 1.2                            | 1.0    | 1.1 | 0.9                    | 1.1    | 1.0 |
|                     | Median             | 2.0                          | 2.0    | 2.0 | 2.0                           | 2.0    | 2.0 | 2.0                            | 3.0    | 2.0 | 2.0                            | 3.0    | 3.0 | 2.0                    | 2.0    | 2.0 |
|                     | Minimum            | 1                            | 1      | 1   | 1                             | 1      | 1   | 1                              | 1      | 1   | 1                              | 1      | 1   | 1                      | 1      | 1   |
|                     | Maximum            | 3                            | 3      | 3   | 4                             | 3      | 4   | 3                              | 5      | 5   | 5                              | 4      | 5   | 5                      | 5      | 5   |
| Erythema/redness    | n                  | -                            | 1      | 1   | 1                             | 4      | 5   | 3                              | 2      | 5   | 3                              | 3      | 6   | 7                      | 10     | 17  |
|                     | Mean               | -                            | 2.0    | 2.0 | 1.0                           | 1.0    | 1.0 | 1.3                            | 3.0    | 2.0 | 1.0                            | 3.3    | 2.2 | 1.1                    | 2.2    | 1.8 |
|                     | Standard Deviation | -                            | .      | .   | .                             | 0.0    | 0.0 | 0.6                            | 2.8    | 1.7 | 0.0                            | 0.6    | 1.3 | 0.4                    | 1.5    | 1.3 |
|                     | Median             | -                            | 2.0    | 2.0 | 1.0                           | 1.0    | 1.0 | 1.0                            | 3.0    | 1.0 | 1.0                            | 3.0    | 2.0 | 1.0                    | 1.5    | 1.0 |
|                     | Minimum            | -                            | 2      | 2   | 1                             | 1      | 1   | 1                              | 1      | 1   | 1                              | 3      | 1   | 1                      | 1      | 1   |
|                     | Maximum            | -                            | 2      | 2   | 1                             | 1      | 1   | 2                              | 5      | 5   | 1                              | 4      | 4   | 2                      | 5      | 5   |
| Induration/swelling | n                  | -                            | -      | -   | 3                             | -      | 3   | 4                              | 1      | 5   | 6                              | 3      | 9   | 13                     | 4      | 17  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 6A:**  
**Summary of Duration of Solicited Symptoms by Vaccination Group - All Subjects 18-55 Years of Age** (*continued*)

|                             |                    | 25 µg<br>mRNA-1273<br>(N=15) |        |     | 50 µg<br>mRNA -1273<br>(N=15) |        |     | 100 µg<br>mRNA -1273<br>(N=15) |        |     | 250 µg<br>mRNA -1273<br>(N=15) |        |     | All Subjects<br>(N=60) |        |     |
|-----------------------------|--------------------|------------------------------|--------|-----|-------------------------------|--------|-----|--------------------------------|--------|-----|--------------------------------|--------|-----|------------------------|--------|-----|
| Variable                    | Statistic          | Dose 1                       | Dose 2 | All | Dose 1                        | Dose 2 | All | Dose 1                         | Dose 2 | All | Dose 1                         | Dose 2 | All | Dose 1                 | Dose 2 | All |
|                             | Mean               | -                            | -      | -   | 2.0                           | -      | 2.0 | 1.8                            | 4.0    | 2.2 | 1.7                            | 2.7    | 2.0 | 1.8                    | 3.0    | 2.1 |
|                             | Standard Deviation | -                            | -      | -   | 1.7                           | -      | 1.7 | 1.0                            | .      | 1.3 | 1.2                            | 0.6    | 1.1 | 1.2                    | 0.8    | 1.2 |
|                             | Median             | -                            | -      | -   | 1.0                           | -      | 1.0 | 1.5                            | 4.0    | 2.0 | 1.0                            | 3.0    | 2.0 | 1.0                    | 3.0    | 2.0 |
|                             | Minimum            | -                            | -      | -   | 1                             | -      | 1   | 1                              | 4      | 1   | 1                              | 2      | 1   | 1                      | 2      | 1   |
|                             | Maximum            | -                            | -      | -   | 4                             | -      | 4   | 3                              | 4      | 4   | 4                              | 3      | 4   | 4                      | 4      | 4   |
| <b>Pain</b>                 | n                  | 10                           | 11     | 21  | 13                            | 13     | 26  | 15                             | 16     | 31  | 16                             | 16     | 32  | 54                     | 56     | 110 |
|                             | Mean               | 1.7                          | 2.0    | 1.9 | 2.2                           | 2.1    | 2.1 | 1.7                            | 2.6    | 2.2 | 2.8                            | 2.5    | 2.6 | 2.1                    | 2.3    | 2.2 |
|                             | Standard Deviation | 0.7                          | 0.9    | 0.8 | 0.7                           | 0.8    | 0.7 | 0.5                            | 1.1    | 0.9 | 1.0                            | 1.1    | 1.0 | 0.8                    | 1.0    | 0.9 |
|                             | Median             | 2.0                          | 2.0    | 2.0 | 2.0                           | 2.0    | 2.0 | 2.0                            | 3.0    | 2.0 | 3.0                            | 3.0    | 3.0 | 2.0                    | 2.0    | 2.0 |
|                             | Minimum            | 1                            | 1      | 1   | 1                             | 1      | 1   | 1                              | 1      | 1   | 1                              | 1      | 1   | 1                      | 1      | 1   |
|                             | Maximum            | 3                            | 3      | 3   | 3                             | 3      | 3   | 2                              | 5      | 5   | 5                              | 4      | 5   | 5                      | 5      | 5   |
| <b>Any SyStemic Symptom</b> | n                  | 11                           | 15     | 26  | 18                            | 35     | 53  | 12                             | 58     | 70  | 22                             | 75     | 97  | 63                     | 183    | 246 |
|                             | Mean               | 1.0                          | 1.1    | 1.1 | 1.7                           | 1.5    | 1.6 | 1.3                            | 1.4    | 1.4 | 2.2                            | 1.7    | 1.8 | 1.7                    | 1.5    | 1.6 |
|                             | Standard Deviation | 0.0                          | 0.4    | 0.3 | 1.3                           | 0.8    | 1.0 | 0.5                            | 0.7    | 0.6 | 1.3                            | 0.9    | 1.0 | 1.1                    | 0.8    | 0.9 |
|                             | Median             | 1.0                          | 1.0    | 1.0 | 1.0                           | 1.0    | 1.0 | 1.0                            | 1.0    | 1.0 | 2.0                            | 1.0    | 2.0 | 1.0                    | 1.0    | 1.0 |
|                             | Minimum            | 1                            | 1      | 1   | 1                             | 1      | 1   | 1                              | 1      | 1   | 1                              | 1      | 1   | 1                      | 1      | 1   |
|                             | Maximum            | 1                            | 2      | 2   | 6                             | 3      | 6   | 2                              | 4      | 4   | 5                              | 6      | 6   | 6                      | 6      | 6   |
| <b>Arthralgia</b>           | n                  | -                            | 2      | 2   | 2                             | 2      | 4   | 2                              | 2      | 4   | 2                              | 8      | 10  | 6                      | 14     | 20  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 6A:**  
**Summary of Duration of Solicited Symptoms by Vaccination Group - All Subjects 18-55 Years of Age** (*continued*)

|                     |                    | 25 µg<br>mRNA-1273<br>(N=15) |        |     | 50 µg<br>mRNA -1273<br>(N=15) |        |     | 100 µg<br>mRNA -1273<br>(N=15) |        |     | 250 µg<br>mRNA -1273<br>(N=15) |        |     | All Subjects<br>(N=60) |        |     |
|---------------------|--------------------|------------------------------|--------|-----|-------------------------------|--------|-----|--------------------------------|--------|-----|--------------------------------|--------|-----|------------------------|--------|-----|
| Variable            | Statistic          | Dose 1                       | Dose 2 | All | Dose 1                        | Dose 2 | All | Dose 1                         | Dose 2 | All | Dose 1                         | Dose 2 | All | Dose 1                 | Dose 2 | All |
|                     | Mean               | -                            | 1.0    | 1.0 | 1.0                           | 2.0    | 1.5 | 1.0                            | 1.0    | 1.0 | 3.0                            | 1.4    | 1.7 | 1.7                    | 1.4    | 1.5 |
|                     | Standard Deviation | -                            | 0.0    | 0.0 | 0.0                           | 1.4    | 1.0 | 0.0                            | 0.0    | 0.0 | 1.4                            | 0.5    | 0.9 | 1.2                    | 0.6    | 0.8 |
|                     | Median             | -                            | 1.0    | 1.0 | 1.0                           | 2.0    | 1.0 | 1.0                            | 1.0    | 1.0 | 3.0                            | 1.0    | 1.5 | 1.0                    | 1.0    | 1.0 |
|                     | Minimum            | -                            | 1      | 1   | 1                             | 1      | 1   | 1                              | 1      | 1   | 2                              | 1      | 1   | 1                      | 1      | 1   |
|                     | Maximum            | -                            | 1      | 1   | 1                             | 3      | 3   | 1                              | 1      | 1   | 4                              | 2      | 4   | 4                      | 3      | 4   |
| <b>Fatigue</b>      | n                  | 4                            | 5      | 9   | 9                             | 11     | 20  | 4                              | 12     | 16  | 5                              | 13     | 18  | 22                     | 41     | 63  |
|                     | Mean               | 1.0                          | 1.2    | 1.1 | 2.1                           | 1.8    | 2.0 | 1.5                            | 1.6    | 1.6 | 3.2                            | 2.4    | 2.6 | 2.0                    | 1.9    | 1.9 |
|                     | Standard Deviation | 0.0                          | 0.4    | 0.3 | 1.6                           | 0.9    | 1.2 | 0.6                            | 0.7    | 0.6 | 1.8                            | 1.4    | 1.5 | 1.5                    | 1.1    | 1.2 |
|                     | Median             | 1.0                          | 1.0    | 1.0 | 2.0                           | 2.0    | 2.0 | 1.5                            | 1.5    | 1.5 | 3.0                            | 2.0    | 2.0 | 1.5                    | 2.0    | 2.0 |
|                     | Minimum            | 1                            | 1      | 1   | 1                             | 1      | 1   | 1                              | 1      | 1   | 1                              | 1      | 1   | 1                      | 1      | 1   |
|                     | Maximum            | 1                            | 2      | 2   | 6                             | 3      | 6   | 2                              | 3      | 3   | 5                              | 6      | 6   | 6                      | 6      | 6   |
| <b>Fever</b>        | n                  | -                            | -      | -   | -                             | 1      | 1   | -                              | 6      | 6   | -                              | 8      | 8   | -                      | 15     | 15  |
|                     | Mean               | -                            | -      | -   | -                             | 1.0    | 1.0 | -                              | 1.2    | 1.2 | -                              | 1.3    | 1.3 | -                      | 1.2    | 1.2 |
|                     | Standard Deviation | -                            | -      | -   | -                             | .      | .   | -                              | 0.4    | 0.4 | -                              | 0.5    | 0.5 | -                      | 0.4    | 0.4 |
|                     | Median             | -                            | -      | -   | -                             | 1.0    | 1.0 | -                              | 1.0    | 1.0 | -                              | 1.0    | 1.0 | -                      | 1.0    | 1.0 |
|                     | Minimum            | -                            | -      | -   | -                             | 1      | 1   | -                              | 1      | 1   | -                              | 1      | 1   | -                      | 1      | 1   |
|                     | Maximum            | -                            | -      | -   | -                             | 1      | 1   | -                              | 2      | 2   | -                              | 2      | 2   | -                      | 2      | 2   |
| <b>Feverishness</b> | n                  | -                            | 1      | 1   | -                             | 3      | 3   | 1                              | 12     | 13  | 2                              | 12     | 14  | 3                      | 28     | 31  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 6A:**  
**Summary of Duration of Solicited Symptoms by Vaccination Group - All Subjects 18-55 Years of Age** (*continued*)

|                 |                    | 25 µg<br>mRNA-1273<br>(N=15) |        |     | 50 µg<br>mRNA -1273<br>(N=15) |        |     | 100 µg<br>mRNA -1273<br>(N=15) |        |     | 250 µg<br>mRNA -1273<br>(N=15) |        |     | All Subjects<br>(N=60) |        |     |
|-----------------|--------------------|------------------------------|--------|-----|-------------------------------|--------|-----|--------------------------------|--------|-----|--------------------------------|--------|-----|------------------------|--------|-----|
| Variable        | Statistic          | Dose 1                       | Dose 2 | All | Dose 1                        | Dose 2 | All | Dose 1                         | Dose 2 | All | Dose 1                         | Dose 2 | All | Dose 1                 | Dose 2 | All |
|                 | Mean               | -                            | 1.0    | 1.0 | -                             | 1.0    | 1.0 | 2.0                            | 1.3    | 1.3 | 1.0                            | 1.6    | 1.5 | 1.3                    | 1.4    | 1.4 |
|                 | Standard Deviation | -                            | .      | .   | -                             | 0.0    | 0.0 | .                              | 0.5    | 0.5 | 0.0                            | 0.5    | 0.5 | 0.6                    | 0.5    | 0.5 |
|                 | Median             | -                            | 1.0    | 1.0 | -                             | 1.0    | 1.0 | 2.0                            | 1.0    | 1.0 | 1.0                            | 2.0    | 1.5 | 1.0                    | 1.0    | 1.0 |
|                 | Minimum            | -                            | 1      | 1   | -                             | 1      | 1   | 2                              | 1      | 1   | 1                              | 1      | 1   | 1                      | 1      | 1   |
|                 | Maximum            | -                            | 1      | 1   | -                             | 1      | 1   | 2                              | 2      | 2   | 1                              | 2      | 2   | 2                      | 2      | 2   |
| <b>Headache</b> | n                  | 5                            | 3      | 8   | 3                             | 10     | 13  | 4                              | 9      | 13  | 8                              | 17     | 25  | 20                     | 39     | 59  |
|                 | Mean               | 1.0                          | 1.0    | 1.0 | 1.7                           | 1.3    | 1.4 | 1.0                            | 1.4    | 1.3 | 1.9                            | 1.6    | 1.7 | 1.5                    | 1.4    | 1.4 |
|                 | Standard Deviation | 0.0                          | 0.0    | 0.0 | 1.2                           | 0.5    | 0.7 | 0.0                            | 1.0    | 0.9 | 1.0                            | 0.8    | 0.9 | 0.8                    | 0.8    | 0.8 |
|                 | Median             | 1.0                          | 1.0    | 1.0 | 1.0                           | 1.0    | 1.0 | 1.0                            | 1.0    | 1.0 | 1.5                            | 1.0    | 1.0 | 1.0                    | 1.0    | 1.0 |
|                 | Minimum            | 1                            | 1      | 1   | 1                             | 1      | 1   | 1                              | 1      | 1   | 1                              | 1      | 1   | 1                      | 1      | 1   |
|                 | Maximum            | 1                            | 1      | 1   | 3                             | 2      | 3   | 1                              | 4      | 4   | 3                              | 3      | 3   | 3                      | 4      | 4   |
| <b>Myalgia</b>  | n                  | 1                            | 3      | 4   | 2                             | 6      | 8   | 1                              | 10     | 11  | 4                              | 13     | 17  | 8                      | 32     | 40  |
|                 | Mean               | 1.0                          | 1.3    | 1.3 | 1.0                           | 1.8    | 1.6 | 1.0                            | 1.7    | 1.6 | 1.8                            | 1.8    | 1.8 | 1.4                    | 1.8    | 1.7 |
|                 | Standard Deviation | .                            | 0.6    | 0.5 | 0.0                           | 1.0    | 0.9 | .                              | 0.8    | 0.8 | 1.0                            | 0.9    | 0.9 | 0.7                    | 0.8    | 0.8 |
|                 | Median             | 1.0                          | 1.0    | 1.0 | 1.0                           | 1.5    | 1.0 | 1.0                            | 1.5    | 1.0 | 1.5                            | 2.0    | 2.0 | 1.0                    | 2.0    | 1.0 |
|                 | Minimum            | 1                            | 1      | 1   | 1                             | 1      | 1   | 1                              | 1      | 1   | 1                              | 1      | 1   | 1                      | 1      | 1   |
|                 | Maximum            | 1                            | 2      | 2   | 1                             | 3      | 3   | 1                              | 3      | 3   | 3                              | 4      | 4   | 3                      | 4      | 4   |
| <b>Nausea</b>   | n                  | 1                            | 1      | 2   | 2                             | 2      | 4   | -                              | 7      | 7   | 1                              | 4      | 5   | 4                      | 14     | 18  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 6A:**  
**Summary of Duration of Solicited Symptoms by Vaccination Group - All Subjects 18-55 Years of Age** (*continued*)

|                                      |                    | 25 µg<br>mRNA-1273<br>(N=15) |        |     | 50 µg<br>mRNA -1273<br>(N=15) |        |     | 100 µg<br>mRNA -1273<br>(N=15) |        |     | 250 µg<br>mRNA -1273<br>(N=15) |        |     | All Subjects<br>(N=60) |        |     |
|--------------------------------------|--------------------|------------------------------|--------|-----|-------------------------------|--------|-----|--------------------------------|--------|-----|--------------------------------|--------|-----|------------------------|--------|-----|
| Variable                             | Statistic          | Dose 1                       | Dose 2 | All | Dose 1                        | Dose 2 | All | Dose 1                         | Dose 2 | All | Dose 1                         | Dose 2 | All | Dose 1                 | Dose 2 | All |
|                                      | Mean               | 1.0                          | 1.0    | 1.0 | 1.0                           | 1.0    | 1.0 | -                              | 1.3    | 1.3 | 2.0                            | 1.0    | 1.2 | 1.3                    | 1.1    | 1.2 |
|                                      | Standard Deviation | .                            | .      | 0.0 | 0.0                           | 0.0    | 0.0 | -                              | 0.5    | 0.5 | .                              | 0.0    | 0.4 | 0.5                    | 0.4    | 0.4 |
|                                      | Median             | 1.0                          | 1.0    | 1.0 | 1.0                           | 1.0    | 1.0 | -                              | 1.0    | 1.0 | 2.0                            | 1.0    | 1.0 | 1.0                    | 1.0    | 1.0 |
|                                      | Minimum            | 1                            | 1      | 1   | 1                             | 1      | 1   | -                              | 1      | 1   | 2                              | 1      | 1   | 1                      | 1      | 1   |
|                                      | Maximum            | 1                            | 1      | 1   | 1                             | 1      | 1   | -                              | 2      | 2   | 2                              | 1      | 2   | 2                      | 2      | 2   |
| n=number of solicited adverse events |                    |                              |        |     |                               |        |     |                                |        |     |                                |        |     |                        |        |     |

**TABLE 6B:**  
**Summary of Duration of Solicited Symptoms by Vaccination Group - All Subjects 56-70 Years of Age**

|                     |                    | 25 µg<br>mRNA-1273<br>(N=10) |        |     | 50 µg<br>mRNA-1273<br>(N=10) |        |     | 100 µg<br>mRNA-1273<br>(N=10) |        |     | All Subjects<br>(N=30) |        |     |
|---------------------|--------------------|------------------------------|--------|-----|------------------------------|--------|-----|-------------------------------|--------|-----|------------------------|--------|-----|
| Variable            | Statistic          | Dose 1                       | Dose 2 | All | Dose 1                       | Dose 2 | All | Dose 1                        | Dose 2 | All | Dose 1                 | Dose 2 | All |
| Any Symptom         | n                  | 19                           | 32     | 51  | 13                           | 24     | 37  | 18                            | 47     | 65  | 50                     | 103    | 153 |
|                     | Mean               | 1.6                          | 1.6    | 1.6 | 1.6                          | 2.0    | 1.9 | 1.3                           | 1.8    | 1.7 | 1.5                    | 1.8    | 1.7 |
|                     | Standard Deviation | 1.6                          | 0.8    | 1.2 | 0.7                          | 1.2    | 1.1 | 0.5                           | 1.0    | 0.9 | 1.1                    | 1.0    | 1.0 |
|                     | Median             | 1.0                          | 1.0    | 1.0 | 2.0                          | 2.0    | 2.0 | 1.0                           | 2.0    | 1.0 | 1.0                    | 1.0    | 1.0 |
|                     | Minimum            | 1                            | 1      | 1   | 1                            | 1      | 1   | 1                             | 1      | 1   | 1                      | 1      | 1   |
|                     | Maximum            | 8                            | 4      | 8   | 3                            | 5      | 5   | 2                             | 5      | 5   | 8                      | 5      | 8   |
| Any Local Symptom   | n                  | 7                            | 12     | 19  | 8                            | 10     | 18  | 12                            | 13     | 25  | 27                     | 35     | 62  |
|                     | Mean               | 2.3                          | 1.8    | 1.9 | 1.9                          | 2.6    | 2.3 | 1.4                           | 2.4    | 1.9 | 1.8                    | 2.2    | 2.0 |
|                     | Standard Deviation | 2.6                          | 0.8    | 1.6 | 0.6                          | 1.3    | 1.1 | 0.5                           | 1.3    | 1.1 | 1.4                    | 1.1    | 1.3 |
|                     | Median             | 1.0                          | 2.0    | 2.0 | 2.0                          | 2.5    | 2.0 | 1.0                           | 2.0    | 2.0 | 2.0                    | 2.0    | 2.0 |
|                     | Minimum            | 1                            | 1      | 1   | 1                            | 1      | 1   | 1                             | 1      | 1   | 1                      | 1      | 1   |
|                     | Maximum            | 8                            | 3      | 8   | 3                            | 5      | 5   | 2                             | 5      | 5   | 8                      | 5      | 8   |
| Erythema/redness    | n                  | 2                            | 2      | 4   | -                            | 1      | 1   | 1                             | 3      | 4   | 3                      | 6      | 9   |
|                     | Mean               | 4.5                          | 2.0    | 3.3 | -                            | 3.0    | 3.0 | 1.0                           | 2.3    | 2.0 | 3.3                    | 2.3    | 2.7 |
|                     | Standard Deviation | 4.9                          | 0.0    | 3.2 | -                            | .      | .   | .                             | 2.3    | 2.0 | 4.0                    | 1.5    | 2.4 |
|                     | Median             | 4.5                          | 2.0    | 2.0 | -                            | 3.0    | 3.0 | 1.0                           | 1.0    | 1.0 | 1.0                    | 2.0    | 2.0 |
|                     | Minimum            | 1                            | 2      | 1   | -                            | 3      | 3   | 1                             | 1      | 1   | 1                      | 1      | 1   |
|                     | Maximum            | 8                            | 2      | 8   | -                            | 3      | 3   | 1                             | 5      | 5   | 8                      | 5      | 8   |
| Induration/swelling | n                  | 2                            | 4      | 6   | 2                            | 1      | 3   | 3                             | 2      | 5   | 7                      | 7      | 14  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**TABLE 6B:**  
**Summary of Duration of Solicited Symptoms by Vaccination Group - All Subjects 56-70 Years of Age** (*continued*)

|                             |                    | 25 µg<br>mRNA-1273<br>(N=10) |        |     | 50 µg<br>mRNA-1273<br>(N=10) |        |     | 100 µg<br>mRNA-1273<br>(N=10) |        |     | All Subjects<br>(N=30) |        |     |
|-----------------------------|--------------------|------------------------------|--------|-----|------------------------------|--------|-----|-------------------------------|--------|-----|------------------------|--------|-----|
| Variable                    | Statistic          | Dose 1                       | Dose 2 | All | Dose 1                       | Dose 2 | All | Dose 1                        | Dose 2 | All | Dose 1                 | Dose 2 | All |
|                             | Mean               | 1.5                          | 1.8    | 1.7 | 1.5                          | 5.0    | 2.7 | 1.3                           | 3.0    | 2.0 | 1.4                    | 2.6    | 2.0 |
|                             | Standard Deviation | 0.7                          | 1.0    | 0.8 | 0.7                          | .      | 2.1 | 0.6                           | 1.4    | 1.2 | 0.5                    | 1.5    | 1.2 |
|                             | Median             | 1.5                          | 1.5    | 1.5 | 1.5                          | 5.0    | 2.0 | 1.0                           | 3.0    | 2.0 | 1.0                    | 2.0    | 2.0 |
|                             | Minimum            | 1                            | 1      | 1   | 1                            | 5      | 1   | 1                             | 2      | 1   | 1                      | 1      | 1   |
|                             | Maximum            | 2                            | 3      | 3   | 2                            | 5      | 5   | 2                             | 4      | 4   | 2                      | 5      | 5   |
| <b>Pain</b>                 | n                  | 3                            | 6      | 9   | 6                            | 8      | 14  | 8                             | 8      | 16  | 17                     | 22     | 39  |
|                             | Mean               | 1.3                          | 1.7    | 1.6 | 2.0                          | 2.3    | 2.1 | 1.5                           | 2.3    | 1.9 | 1.6                    | 2.1    | 1.9 |
|                             | Standard Deviation | 0.6                          | 0.8    | 0.7 | 0.6                          | 1.0    | 0.9 | 0.5                           | 0.9    | 0.8 | 0.6                    | 0.9    | 0.8 |
|                             | Median             | 1.0                          | 1.5    | 1.0 | 2.0                          | 2.0    | 2.0 | 1.5                           | 2.0    | 2.0 | 2.0                    | 2.0    | 2.0 |
|                             | Minimum            | 1                            | 1      | 1   | 1                            | 1      | 1   | 1                             | 1      | 1   | 1                      | 1      | 1   |
|                             | Maximum            | 2                            | 3      | 3   | 3                            | 4      | 4   | 2                             | 4      | 4   | 3                      | 4      | 4   |
| <b>Any SyStemic Symptom</b> | n                  | 12                           | 20     | 32  | 5                            | 14     | 19  | 6                             | 34     | 40  | 23                     | 68     | 91  |
|                             | Mean               | 1.3                          | 1.5    | 1.4 | 1.2                          | 1.6    | 1.5 | 1.2                           | 1.6    | 1.5 | 1.2                    | 1.5    | 1.5 |
|                             | Standard Deviation | 0.5                          | 0.9    | 0.8 | 0.4                          | 1.1    | 1.0 | 0.4                           | 0.8    | 0.8 | 0.4                    | 0.9    | 0.8 |
|                             | Median             | 1.0                          | 1.0    | 1.0 | 1.0                          | 1.0    | 1.0 | 1.0                           | 1.0    | 1.0 | 1.0                    | 1.0    | 1.0 |
|                             | Minimum            | 1                            | 1      | 1   | 1                            | 1      | 1   | 1                             | 1      | 1   | 1                      | 1      | 1   |
|                             | Maximum            | 2                            | 4      | 4   | 2                            | 5      | 5   | 2                             | 4      | 4   | 2                      | 5      | 5   |
| <b>Arthralgia</b>           | n                  | 5                            | 1      | 6   | -                            | 1      | 1   | -                             | 2      | 2   | 5                      | 4      | 9   |

**TABLE 6B:**  
**Summary of Duration of Solicited Symptoms by Vaccination Group - All Subjects 56-70 Years of Age** (*continued*)

|                     |                    | 25 µg<br>mRNA-1273<br>(N=10) |        |     | 50 µg<br>mRNA-1273<br>(N=10) |        |     | 100 µg<br>mRNA-1273<br>(N=10) |        |     | All Subjects<br>(N=30) |        |     |
|---------------------|--------------------|------------------------------|--------|-----|------------------------------|--------|-----|-------------------------------|--------|-----|------------------------|--------|-----|
| Variable            | Statistic          | Dose 1                       | Dose 2 | All | Dose 1                       | Dose 2 | All | Dose 1                        | Dose 2 | All | Dose 1                 | Dose 2 | All |
|                     | Mean               | 1.2                          | 1.0    | 1.2 | -                            | 2.0    | 2.0 | -                             | 2.0    | 2.0 | 1.2                    | 1.8    | 1.4 |
|                     | Standard Deviation | 0.4                          | .      | 0.4 | -                            | .      | .   | -                             | 0.0    | 0.0 | 0.4                    | 0.5    | 0.5 |
|                     | Median             | 1.0                          | 1.0    | 1.0 | -                            | 2.0    | 2.0 | -                             | 2.0    | 2.0 | 1.0                    | 2.0    | 1.0 |
|                     | Minimum            | 1                            | 1      | 1   | -                            | 2      | 2   | -                             | 2      | 2   | 1                      | 1      | 1   |
|                     | Maximum            | 2                            | 1      | 2   | -                            | 2      | 2   | -                             | 2      | 2   | 2                      | 2      | 2   |
| <b>Fatigue</b>      | n                  | 2                            | 5      | 7   | 1                            | 5      | 6   | 5                             | 7      | 12  | 8                      | 17     | 25  |
|                     | Mean               | 1.5                          | 1.8    | 1.7 | 1.0                          | 2.4    | 2.2 | 1.2                           | 2.1    | 1.8 | 1.3                    | 2.1    | 1.8 |
|                     | Standard Deviation | 0.7                          | 1.1    | 1.0 | .                            | 1.5    | 1.5 | 0.4                           | 1.2    | 1.1 | 0.5                    | 1.2    | 1.1 |
|                     | Median             | 1.5                          | 1.0    | 1.0 | 1.0                          | 2.0    | 2.0 | 1.0                           | 2.0    | 1.0 | 1.0                    | 2.0    | 1.0 |
|                     | Minimum            | 1                            | 1      | 1   | 1                            | 1      | 1   | 1                             | 1      | 1   | 1                      | 1      | 1   |
|                     | Maximum            | 2                            | 3      | 3   | 1                            | 5      | 5   | 2                             | 4      | 4   | 2                      | 5      | 5   |
| <b>Fever</b>        | n                  | -                            | 1      | 1   | -                            | 1      | 1   | -                             | 1      | 1   | -                      | 3      | 3   |
|                     | Mean               | -                            | 2.0    | 2.0 | -                            | 1.0    | 1.0 | -                             | 1.0    | 1.0 | -                      | 1.3    | 1.3 |
|                     | Standard Deviation | -                            | .      | .   | -                            | .      | .   | -                             | .      | .   | -                      | 0.6    | 0.6 |
|                     | Median             | -                            | 2.0    | 2.0 | -                            | 1.0    | 1.0 | -                             | 1.0    | 1.0 | -                      | 1.0    | 1.0 |
|                     | Minimum            | -                            | 2      | 2   | -                            | 1      | 1   | -                             | 1      | 1   | -                      | 1      | 1   |
|                     | Maximum            | -                            | 2      | 2   | -                            | 1      | 1   | -                             | 1      | 1   | -                      | 2      | 2   |
| <b>Feverishness</b> | n                  | -                            | 2      | 2   | -                            | 2      | 2   | -                             | 5      | 5   | -                      | 9      | 9   |

**TABLE 6B:**  
**Summary of Duration of Solicited Symptoms by Vaccination Group - All Subjects 56-70 Years of Age** (*continued*)

|          |                    | 25 µg<br>mRNA-1273<br>(N=10) |        |     | 50 µg<br>mRNA-1273<br>(N=10) |        |     | 100 µg<br>mRNA-1273<br>(N=10) |        |     | All Subjects<br>(N=30) |        |     |
|----------|--------------------|------------------------------|--------|-----|------------------------------|--------|-----|-------------------------------|--------|-----|------------------------|--------|-----|
| Variable | Statistic          | Dose 1                       | Dose 2 | All | Dose 1                       | Dose 2 | All | Dose 1                        | Dose 2 | All | Dose 1                 | Dose 2 | All |
|          | Mean               | -                            | 1.0    | 1.0 | -                            | 1.0    | 1.0 | -                             | 1.2    | 1.2 | -                      | 1.1    | 1.1 |
|          | Standard Deviation | -                            | 0.0    | 0.0 | -                            | 0.0    | 0.0 | -                             | 0.4    | 0.4 | -                      | 0.3    | 0.3 |
|          | Median             | -                            | 1.0    | 1.0 | -                            | 1.0    | 1.0 | -                             | 1.0    | 1.0 | -                      | 1.0    | 1.0 |
|          | Minimum            | -                            | 1      | 1   | -                            | 1      | 1   | -                             | 1      | 1   | -                      | 1      | 1   |
|          | Maximum            | -                            | 1      | 1   | -                            | 1      | 1   | -                             | 2      | 2   | -                      | 2      | 2   |
| Headache | n                  | 3                            | 3      | 6   | 1                            | 3      | 4   | -                             | 8      | 8   | 4                      | 14     | 18  |
|          | Mean               | 1.0                          | 1.3    | 1.2 | 1.0                          | 1.0    | 1.0 | -                             | 1.4    | 1.4 | 1.0                    | 1.3    | 1.2 |
|          | Standard Deviation | 0.0                          | 0.6    | 0.4 | .                            | 0.0    | 0.0 | -                             | 0.5    | 0.5 | 0.0                    | 0.5    | 0.4 |
|          | Median             | 1.0                          | 1.0    | 1.0 | 1.0                          | 1.0    | 1.0 | -                             | 1.0    | 1.0 | 1.0                    | 1.0    | 1.0 |
|          | Minimum            | 1                            | 1      | 1   | 1                            | 1      | 1   | -                             | 1      | 1   | 1                      | 1      | 1   |
|          | Maximum            | 1                            | 2      | 2   | 1                            | 1      | 1   | -                             | 2      | 2   | 1                      | 2      | 2   |
| Myalgia  | n                  | 2                            | 6      | 8   | 1                            | 2      | 3   | 1                             | 7      | 8   | 4                      | 15     | 19  |
|          | Mean               | 1.5                          | 1.5    | 1.5 | 2.0                          | 1.5    | 1.7 | 1.0                           | 1.6    | 1.5 | 1.5                    | 1.5    | 1.5 |
|          | Standard Deviation | 0.7                          | 1.2    | 1.1 | .                            | 0.7    | 0.6 | .                             | 0.8    | 0.8 | 0.6                    | 0.9    | 0.8 |
|          | Median             | 1.5                          | 1.0    | 1.0 | 2.0                          | 1.5    | 2.0 | 1.0                           | 1.0    | 1.0 | 1.5                    | 1.0    | 1.0 |
|          | Minimum            | 1                            | 1      | 1   | 2                            | 1      | 1   | 1                             | 1      | 1   | 1                      | 1      | 1   |
|          | Maximum            | 2                            | 4      | 4   | 2                            | 2      | 2   | 1                             | 3      | 3   | 2                      | 4      | 4   |
| Nausea   | n                  | -                            | 2      | 2   | 2                            | -      | 2   | -                             | 4      | 4   | 2                      | 6      | 8   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 6B:**  
**Summary of Duration of Solicited Symptoms by Vaccination Group - All Subjects 56-70 Years of Age** (*continued*)

|                                      |                    | 25 µg<br>mRNA-1273<br>(N=10) |        |     | 50 µg<br>mRNA-1273<br>(N=10) |        |     | 100 µg<br>mRNA-1273<br>(N=10) |        |     | All Subjects<br>(N=30) |        |     |
|--------------------------------------|--------------------|------------------------------|--------|-----|------------------------------|--------|-----|-------------------------------|--------|-----|------------------------|--------|-----|
| Variable                             | Statistic          | Dose 1                       | Dose 2 | All | Dose 1                       | Dose 2 | All | Dose 1                        | Dose 2 | All | Dose 1                 | Dose 2 | All |
|                                      | Mean               | -                            | 1.0    | 1.0 | 1.0                          | -      | 1.0 | -                             | 1.3    | 1.3 | 1.0                    | 1.2    | 1.1 |
|                                      | Standard Deviation | -                            | 0.0    | 0.0 | 0.0                          | -      | 0.0 | -                             | 0.5    | 0.5 | 0.0                    | 0.4    | 0.4 |
|                                      | Median             | -                            | 1.0    | 1.0 | 1.0                          | -      | 1.0 | -                             | 1.0    | 1.0 | 1.0                    | 1.0    | 1.0 |
|                                      | Minimum            | -                            | 1      | 1   | 1                            | -      | 1   | -                             | 1      | 1   | 1                      | 1      | 1   |
|                                      | Maximum            | -                            | 1      | 1   | 1                            | -      | 1   | -                             | 2      | 2   | 1                      | 2      | 2   |
| n=number of solicited adverse events |                    |                              |        |     |                              |        |     |                               |        |     |                        |        |     |

**TABLE 6C:**  
**Summary of Duration of Solicited Symptoms by Vaccination Group - All Subjects  $\geq 71$  Years of Age**

|                     |                    | 25 µg<br>mRNA-1273<br>(N=10) |       |     | 50 µg<br>mRNA-1273<br>(N=10) |       |     | 100 µg<br>mRNA-1273<br>(N=10) |       |     | All Subjects<br>(N=30) |       |     |
|---------------------|--------------------|------------------------------|-------|-----|------------------------------|-------|-----|-------------------------------|-------|-----|------------------------|-------|-----|
| Variable            | Statistic          | Dose1                        | Dose2 | All | Dose1                        | Dose2 | All | Dose1                         | Dose2 | All | Dose1                  | Dose2 | All |
| Any Symptom         | n                  | 18                           | 16    | 34  | 19                           | 12    | 31  | 14                            | 47    | 61  | 51                     | 75    | 126 |
|                     | Mean               | 1.7                          | 1.8   | 1.7 | 1.9                          | 2.1   | 2.0 | 1.7                           | 1.7   | 1.7 | 1.8                    | 1.8   | 1.8 |
|                     | Standard Deviation | 1.3                          | 1.4   | 1.3 | 1.4                          | 1.2   | 1.3 | 0.7                           | 1.0   | 1.0 | 1.2                    | 1.1   | 1.2 |
|                     | Median             | 1.0                          | 1.0   | 1.0 | 1.0                          | 2.0   | 1.0 | 2.0                           | 1.0   | 1.0 | 1.0                    | 1.0   | 1.0 |
|                     | Minimum            | 1                            | 1     | 1   | 1                            | 1     | 1   | 1                             | 1     | 1   | 1                      | 1     | 1   |
|                     | Maximum            | 6                            | 6     | 6   | 5                            | 5     | 5   | 3                             | 4     | 4   | 6                      | 6     | 6   |
| Any Local Symptom   | n                  | 7                            | 12    | 19  | 12                           | 5     | 17  | 8                             | 18    | 26  | 27                     | 35    | 62  |
|                     | Mean               | 1.7                          | 2.1   | 1.9 | 2.2                          | 2.2   | 2.2 | 1.9                           | 2.3   | 2.2 | 2.0                    | 2.2   | 2.1 |
|                     | Standard Deviation | 0.8                          | 1.6   | 1.3 | 1.6                          | 0.8   | 1.4 | 0.6                           | 1.2   | 1.1 | 1.2                    | 1.3   | 1.2 |
|                     | Median             | 2.0                          | 1.5   | 2.0 | 1.0                          | 2.0   | 2.0 | 2.0                           | 2.0   | 2.0 | 2.0                    | 2.0   | 2.0 |
|                     | Minimum            | 1                            | 1     | 1   | 1                            | 1     | 1   | 1                             | 1     | 1   | 1                      | 1     | 1   |
|                     | Maximum            | 3                            | 6     | 6   | 5                            | 3     | 5   | 3                             | 4     | 4   | 5                      | 6     | 6   |
| Erythema/redness    | n                  | 1                            | 3     | 4   | 1                            | -     | 1   | -                             | 4     | 4   | 2                      | 7     | 9   |
|                     | Mean               | 2.0                          | 3.0   | 2.8 | 4.0                          | -     | 4.0 | -                             | 2.3   | 2.3 | 3.0                    | 2.6   | 2.7 |
|                     | Standard Deviation | .                            | 2.6   | 2.2 | .                            | -     | .   | -                             | 1.3   | 1.3 | 1.4                    | 1.8   | 1.7 |
|                     | Median             | 2.0                          | 2.0   | 2.0 | 4.0                          | -     | 4.0 | -                             | 2.0   | 2.0 | 3.0                    | 2.0   | 2.0 |
|                     | Minimum            | 2                            | 1     | 1   | 4                            | -     | 4   | -                             | 1     | 1   | 2                      | 1     | 1   |
|                     | Maximum            | 2                            | 6     | 6   | 4                            | -     | 4   | -                             | 4     | 4   | 4                      | 6     | 6   |
| Induration/swelling | n                  | -                            | 2     | 2   | 4                            | -     | 4   | -                             | 3     | 3   | 4                      | 5     | 9   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 6C:**  
**Summary of Duration of Solicited Symptoms by Vaccination Group - All Subjects  $\geq 71$  Years of Age (continued)**

|                             |                    | 25 µg<br>mRNA-1273<br>(N=10) |       |     | 50 µg<br>mRNA-1273<br>(N=10) |       |     | 100 µg<br>mRNA-1273<br>(N=10) |       |     | All Subjects<br>(N=30) |       |     |
|-----------------------------|--------------------|------------------------------|-------|-----|------------------------------|-------|-----|-------------------------------|-------|-----|------------------------|-------|-----|
| Variable                    | Statistic          | Dose1                        | Dose2 | All | Dose1                        | Dose2 | All | Dose1                         | Dose2 | All | Dose1                  | Dose2 | All |
|                             | Mean               | -                            | 2.0   | 2.0 | 2.5                          | -     | 2.5 | -                             | 2.0   | 2.0 | 2.5                    | 2.0   | 2.2 |
|                             | Standard Deviation | -                            | 0.0   | 0.0 | 1.9                          | -     | 1.9 | -                             | 1.7   | 1.7 | 1.9                    | 1.2   | 1.5 |
|                             | Median             | -                            | 2.0   | 2.0 | 2.0                          | -     | 2.0 | -                             | 1.0   | 1.0 | 2.0                    | 2.0   | 2.0 |
|                             | Minimum            | -                            | 2     | 2   | 1                            | -     | 1   | -                             | 1     | 1   | 1                      | 1     | 1   |
|                             | Maximum            | -                            | 2     | 2   | 5                            | -     | 5   | -                             | 4     | 4   | 5                      | 4     | 5   |
| <b>Pain</b>                 | n                  | 6                            | 7     | 13  | 7                            | 5     | 12  | 8                             | 11    | 19  | 21                     | 23    | 44  |
|                             | Mean               | 1.7                          | 1.7   | 1.7 | 1.7                          | 2.2   | 1.9 | 1.9                           | 2.5   | 2.2 | 1.8                    | 2.2   | 2.0 |
|                             | Standard Deviation | 0.8                          | 1.3   | 1.0 | 1.5                          | 0.8   | 1.2 | 0.6                           | 1.2   | 1.0 | 1.0                    | 1.2   | 1.1 |
|                             | Median             | 1.5                          | 1.0   | 1.0 | 1.0                          | 2.0   | 1.5 | 2.0                           | 2.0   | 2.0 | 2.0                    | 2.0   | 2.0 |
|                             | Minimum            | 1                            | 1     | 1   | 1                            | 1     | 1   | 1                             | 1     | 1   | 1                      | 1     | 1   |
|                             | Maximum            | 3                            | 4     | 4   | 5                            | 3     | 5   | 3                             | 4     | 4   | 5                      | 4     | 5   |
| <b>Any SyStemic Symptom</b> | n                  | 11                           | 4     | 15  | 7                            | 7     | 14  | 6                             | 29    | 35  | 24                     | 40    | 64  |
|                             | Mean               | 1.6                          | 1.0   | 1.5 | 1.4                          | 2.0   | 1.7 | 1.5                           | 1.2   | 1.3 | 1.5                    | 1.4   | 1.4 |
|                             | Standard Deviation | 1.6                          | 0.0   | 1.4 | 0.8                          | 1.5   | 1.2 | 0.8                           | 0.6   | 0.6 | 1.2                    | 0.8   | 1.0 |
|                             | Median             | 1.0                          | 1.0   | 1.0 | 1.0                          | 1.0   | 1.0 | 1.0                           | 1.0   | 1.0 | 1.0                    | 1.0   | 1.0 |
|                             | Minimum            | 1                            | 1     | 1   | 1                            | 1     | 1   | 1                             | 1     | 1   | 1                      | 1     | 1   |
|                             | Maximum            | 6                            | 1     | 6   | 3                            | 5     | 5   | 3                             | 3     | 3   | 6                      | 5     | 6   |
| <b>Arthralgia</b>           | n                  | 1                            | -     | 1   | 1                            | -     | 1   | -                             | 3     | 3   | 2                      | 3     | 5   |

**TABLE 6C:**  
**Summary of Duration of Solicited Symptoms by Vaccination Group - All Subjects  $\geq 71$  Years of Age** *(continued)*

|                     |                    | 25 µg<br>mRNA-1273<br>(N=10) |       |     | 50 µg<br>mRNA-1273<br>(N=10) |       |     | 100 µg<br>mRNA-1273<br>(N=10) |       |     | All Subjects<br>(N=30) |       |     |
|---------------------|--------------------|------------------------------|-------|-----|------------------------------|-------|-----|-------------------------------|-------|-----|------------------------|-------|-----|
| Variable            | Statistic          | Dose1                        | Dose2 | All | Dose1                        | Dose2 | All | Dose1                         | Dose2 | All | Dose1                  | Dose2 | All |
|                     | Mean               | 1.0                          | -     | 1.0 | 2.0                          | -     | 2.0 | -                             | 1.0   | 1.0 | 1.5                    | 1.0   | 1.2 |
|                     | Standard Deviation | .                            | -     | .   | .                            | -     | .   | -                             | 0.0   | 0.0 | 0.7                    | 0.0   | 0.4 |
|                     | Median             | 1.0                          | -     | 1.0 | 2.0                          | -     | 2.0 | -                             | 1.0   | 1.0 | 1.5                    | 1.0   | 1.0 |
|                     | Minimum            | 1                            | -     | 1   | 2                            | -     | 2   | -                             | 1     | 1   | 1                      | 1     | 1   |
|                     | Maximum            | 1                            | -     | 1   | 2                            | -     | 2   | -                             | 1     | 1   | 2                      | 1     | 2   |
| <b>Fatigue</b>      | n                  | 3                            | 1     | 4   | 5                            | 5     | 10  | 3                             | 9     | 12  | 11                     | 15    | 26  |
|                     | Mean               | 1.7                          | 1.0   | 1.5 | 1.4                          | 2.0   | 1.7 | 2.0                           | 1.4   | 1.6 | 1.6                    | 1.6   | 1.6 |
|                     | Standard Deviation | 1.2                          | .     | 1.0 | 0.9                          | 1.7   | 1.3 | 1.0                           | 0.7   | 0.8 | 0.9                    | 1.1   | 1.0 |
|                     | Median             | 1.0                          | 1.0   | 1.0 | 1.0                          | 1.0   | 1.0 | 2.0                           | 1.0   | 1.0 | 1.0                    | 1.0   | 1.0 |
|                     | Minimum            | 1                            | 1     | 1   | 1                            | 1     | 1   | 1                             | 1     | 1   | 1                      | 1     | 1   |
|                     | Maximum            | 3                            | 1     | 3   | 3                            | 5     | 5   | 3                             | 3     | 3   | 3                      | 5     | 5   |
| <b>Fever</b>        | n                  | -                            | -     | -   | -                            | -     | -   | -                             | 1     | 1   | -                      | 1     | 1   |
|                     | Mean               | -                            | -     | -   | -                            | -     | -   | -                             | 1.0   | 1.0 | -                      | 1.0   | 1.0 |
|                     | Standard Deviation | -                            | -     | -   | -                            | -     | -   | -                             | .     | .   | -                      | .     | .   |
|                     | Median             | -                            | -     | -   | -                            | -     | -   | -                             | 1.0   | 1.0 | -                      | 1.0   | 1.0 |
|                     | Minimum            | -                            | -     | -   | -                            | -     | -   | -                             | 1     | 1   | -                      | 1     | 1   |
|                     | Maximum            | -                            | -     | -   | -                            | -     | -   | -                             | 1     | 1   | -                      | 1     | 1   |
| <b>Feverishness</b> | n                  | -                            | -     | -   | -                            | -     | -   | 1                             | 4     | 5   | 1                      | 4     | 5   |

**TABLE 6C:**  
**Summary of Duration of Solicited Symptoms by Vaccination Group - All Subjects  $\geq 71$  Years of Age (continued)**

|                 |                    | 25 µg<br>mRNA-1273<br>(N=10) |       |     | 50 µg<br>mRNA-1273<br>(N=10) |       |     | 100 µg<br>mRNA-1273<br>(N=10) |       |     | All Subjects<br>(N=30) |       |     |
|-----------------|--------------------|------------------------------|-------|-----|------------------------------|-------|-----|-------------------------------|-------|-----|------------------------|-------|-----|
| Variable        | Statistic          | Dose1                        | Dose2 | All | Dose1                        | Dose2 | All | Dose1                         | Dose2 | All | Dose1                  | Dose2 | All |
|                 | Mean               | -                            | -     | -   | -                            | -     | -   | 1.0                           | 1.0   | 1.0 | 1.0                    | 1.0   | 1.0 |
|                 | Standard Deviation | -                            | -     | -   | -                            | -     | -   | .                             | 0.0   | 0.0 | .                      | 0.0   | 0.0 |
|                 | Median             | -                            | -     | -   | -                            | -     | -   | 1.0                           | 1.0   | 1.0 | 1.0                    | 1.0   | 1.0 |
|                 | Minimum            | -                            | -     | -   | -                            | -     | -   | 1                             | 1     | 1   | 1                      | 1     | 1   |
|                 | Maximum            | -                            | -     | -   | -                            | -     | -   | 1                             | 1     | 1   | 1                      | 1     | 1   |
| <b>Headache</b> | n                  | 3                            | 2     | 5   | 1                            | -     | 1   | -                             | 4     | 4   | 4                      | 6     | 10  |
|                 | Mean               | 1.0                          | 1.0   | 1.0 | 1.0                          | -     | 1.0 | -                             | 1.5   | 1.5 | 1.0                    | 1.3   | 1.2 |
|                 | Standard Deviation | 0.0                          | 0.0   | 0.0 | .                            | -     | .   | -                             | 1.0   | 1.0 | 0.0                    | 0.8   | 0.6 |
|                 | Median             | 1.0                          | 1.0   | 1.0 | 1.0                          | -     | 1.0 | -                             | 1.0   | 1.0 | 1.0                    | 1.0   | 1.0 |
|                 | Minimum            | 1                            | 1     | 1   | 1                            | -     | 1   | -                             | 1     | 1   | 1                      | 1     | 1   |
|                 | Maximum            | 1                            | 1     | 1   | 1                            | -     | 1   | -                             | 3     | 3   | 1                      | 3     | 3   |
| <b>Myalgia</b>  | n                  | 4                            | 1     | 5   | -                            | 2     | 2   | 2                             | 7     | 9   | 6                      | 10    | 16  |
|                 | Mean               | 2.3                          | 1.0   | 2.0 | -                            | 2.0   | 2.0 | 1.0                           | 1.1   | 1.1 | 1.8                    | 1.3   | 1.5 |
|                 | Standard Deviation | 2.5                          | .     | 2.2 | -                            | 1.4   | 1.4 | 0.0                           | 0.4   | 0.3 | 2.0                    | 0.7   | 1.3 |
|                 | Median             | 1.0                          | 1.0   | 1.0 | -                            | 2.0   | 2.0 | 1.0                           | 1.0   | 1.0 | 1.0                    | 1.0   | 1.0 |
|                 | Minimum            | 1                            | 1     | 1   | -                            | 1     | 1   | 1                             | 1     | 1   | 1                      | 1     | 1   |
|                 | Maximum            | 6                            | 1     | 6   | -                            | 3     | 3   | 1                             | 2     | 2   | 6                      | 3     | 6   |
| <b>Nausea</b>   | n                  | -                            | -     | -   | -                            | -     | -   | -                             | 1     | 1   | -                      | 1     | 1   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**TABLE 6C:**  
**Summary of Duration of Solicited Symptoms by Vaccination Group - All Subjects  $\geq 71$  Years of Age** (*continued*)

|                                      |                    | 25 µg<br>mRNA-1273<br>(N=10) |       |     | 50 µg<br>mRNA-1273<br>(N=10) |       |     | 100 µg<br>mRNA-1273<br>(N=10) |       |     | All Subjects<br>(N=30) |       |     |
|--------------------------------------|--------------------|------------------------------|-------|-----|------------------------------|-------|-----|-------------------------------|-------|-----|------------------------|-------|-----|
| Variable                             | Statistic          | Dose1                        | Dose2 | All | Dose1                        | Dose2 | All | Dose1                         | Dose2 | All | Dose1                  | Dose2 | All |
|                                      | Mean               | -                            | -     | -   | -                            | -     | -   | -                             | 1.0   | 1.0 | -                      | 1.0   | 1.0 |
|                                      | Standard Deviation | -                            | -     | -   | -                            | -     | -   | -                             | .     | .   | -                      | .     | .   |
|                                      | Median             | -                            | -     | -   | -                            | -     | -   | -                             | 1.0   | 1.0 | -                      | 1.0   | 1.0 |
|                                      | Minimum            | -                            | -     | -   | -                            | -     | -   | -                             | 1     | 1   | -                      | 1     | 1   |
|                                      | Maximum            | -                            | -     | -   | -                            | -     | -   | -                             | 1     | 1   | -                      | 1     | 1   |
| n=number of solicited adverse events |                    |                              |       |     |                              |       |     |                               |       |     |                        |       |     |

**TABLE 7A:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group - Any Hematology Parameter**

|                              |                      |     |     | None |     | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|------------------------------|----------------------|-----|-----|------|-----|------------------|----|----------------------|---|--------------------|---|
| Timepoint                    | Study Group          | N   | N*  | n    | %   | n                | %  | n                    | % | n                  | % |
| Screening<br>(Day -42 to -1) | 25 µg (18-55 years)  | 15  | 15  | 13   | 87  | 2                | 13 | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 14   | 93  | 1                | 7  | -                    | - | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                | 7  | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                | 7  | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 100 µg (56-70 years) | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | - |
|                              | 25 µg (≥71 years)    | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | - |
|                              | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 100 µg (≥71 years)   | 10  | 10  | 8    | 80  | 2                | 20 | -                    | - | -                  | - |
|                              | All Subjects         | 120 | 120 | 111  | 93  | 9                | 8  | -                    | - | -                  | - |
| Day 1, Baseline              | 25 µg (18-55 years)  | 15  | 15  | 10   | 67  | 5                | 33 | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 11   | 73  | 4                | 27 | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                | 7  | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7A:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group - Any Hematology Parameter** *(continued)*

|                        |                      |     |     | None |     | Mild/<br>Grade 1 |     | Moderate/<br>Grade 2 |    | Severe/<br>Grade 3 |   |
|------------------------|----------------------|-----|-----|------|-----|------------------|-----|----------------------|----|--------------------|---|
| Timepoint              | Study Group          | N   | N*  | n    | %   | n                | %   | n                    | %  | n                  | % |
|                        | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -   | -                    | -  | -                  | - |
|                        | 25 µg (≥71 years)    | 10  | 10  | 9    | 90  | 1                | 10  | -                    | -  | -                  | - |
|                        | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -   | -                    | -  | -                  | - |
|                        | 100 µg (≥71 years)   | 10  | 10  | 6    | 60  | 3                | 30  | 1                    | 10 | -                  | - |
|                        | All Subjects         | 120 | 120 | 104  | 87  | 15               | 13  | 1                    | 1  | -                  | - |
| Day 8<br>(Days 7 to 9) | 25 µg (18-55 years)  | 15  | 14  | 5    | 36  | 9                | 64  | -                    | -  | -                  | - |
|                        | 50 µg (18-55 years)  | 15  | 15  | 1    | 7   | 13               | 87  | 1                    | 7  | -                  | - |
|                        | 100 µg (18-55 years) | 15  | 15  | 5    | 33  | 10               | 67  | -                    | -  | -                  | - |
|                        | 250 µg (18-55 years) | 15  | 15  | 2    | 13  | 12               | 80  | 1                    | 7  | -                  | - |
|                        | 25 µg (56-70 years)  | 10  | 10  | 1    | 10  | 7                | 70  | 2                    | 20 | -                  | - |
|                        | 50 µg (56-70 years)  | 10  | 10  | 1    | 10  | 9                | 90  | -                    | -  | -                  | - |
|                        | 100 µg (56-70 years) | 10  | 10  | 1    | 10  | 9                | 90  | -                    | -  | -                  | - |
|                        | 25 µg (≥71 years)    | 10  | 10  | 1    | 10  | 9                | 90  | -                    | -  | -                  | - |
|                        | 50 µg (≥71 years)    | 10  | 10  | 2    | 20  | 8                | 80  | -                    | -  | -                  | - |
|                        | 100 µg (≥71 years)   | 10  | 10  | -    | -   | 10               | 100 | -                    | -  | -                  | - |
|                        | All Subjects         | 120 | 119 | 19   | 16  | 96               | 81  | 4                    | 3  | -                  | - |
|                        | 25 µg (18-55 years)  | 15  | 15  | 3    | 20  | 12               | 80  | -                    | -  | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7A:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group - Any Hematology Parameter** *(continued)*

|                                  |                      |     |     | None |    | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |    | Severe/<br>Grade 3 |    |
|----------------------------------|----------------------|-----|-----|------|----|------------------|----|----------------------|----|--------------------|----|
| Timepoint                        | Study Group          | N   | N*  | n    | %  | n                | %  | n                    | %  | n                  | %  |
| <b>Day 29</b><br>(Days 27 to 31) | 50 µg (18-55 years)  | 15  | 15  | 5    | 33 | 10               | 67 | -                    | -  | -                  | -  |
|                                  | 100 µg (18-55 years) | 15  | 15  | 6    | 40 | 9                | 60 | -                    | -  | -                  | -  |
|                                  | 250 µg (18-55 years) | 15  | 14  | 4    | 29 | 10               | 71 | -                    | -  | -                  | -  |
|                                  | 25 µg (56-70 years)  | 10  | 10  | 1    | 10 | 7                | 70 | 1                    | 10 | 1                  | 10 |
|                                  | 50 µg (56-70 years)  | 10  | 10  | 1    | 10 | 9                | 90 | -                    | -  | -                  | -  |
|                                  | 100 µg (56-70 years) | 10  | 10  | 1    | 10 | 9                | 90 | -                    | -  | -                  | -  |
|                                  | 25 µg (≥71 years)    | 10  | 10  | 5    | 50 | 5                | 50 | -                    | -  | -                  | -  |
|                                  | 50 µg (≥71 years)    | 10  | 10  | 4    | 40 | 6                | 60 | -                    | -  | -                  | -  |
|                                  | 100 µg (≥71 years)   | 10  | 10  | 3    | 30 | 7                | 70 | -                    | -  | -                  | -  |
|                                  | All Subjects         | 120 | 119 | 33   | 28 | 84               | 71 | 1                    | 1  | 1                  | 1  |
| <b>Day 36</b><br>(Days 35 to 37) | 25 µg (18-55 years)  | 15  | 15  | 6    | 40 | 9                | 60 | -                    | -  | -                  | -  |
|                                  | 50 µg (18-55 years)  | 15  | 15  | 2    | 13 | 11               | 73 | 2                    | 13 | -                  | -  |
|                                  | 100 µg (18-55 years) | 15  | 15  | 4    | 27 | 11               | 73 | -                    | -  | -                  | -  |
|                                  | 250 µg (18-55 years) | 15  | 15  | 2    | 13 | 11               | 73 | 2                    | 13 | -                  | -  |
|                                  | 25 µg (56-70 years)  | 10  | 10  | 3    | 30 | 7                | 70 | -                    | -  | -                  | -  |
|                                  | 50 µg (56-70 years)  | 10  | 10  | 1    | 10 | 9                | 90 | -                    | -  | -                  | -  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7A:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group - Any Hematology Parameter** *(continued)*

|                            |                      |     |     | None |    | Mild/<br>Grade 1 |     | Moderate/<br>Grade 2 |    | Severe/<br>Grade 3 |    |
|----------------------------|----------------------|-----|-----|------|----|------------------|-----|----------------------|----|--------------------|----|
| Timepoint                  | Study Group          | N   | N*  | n    | %  | n                | %   | n                    | %  | n                  | %  |
|                            | 100 µg (56-70 years) | 10  | 10  | -    | -  | 9                | 90  | 1                    | 10 | -                  | -  |
|                            | 25 µg (≥71 years)    | 10  | 10  | 4    | 40 | 6                | 60  | -                    | -  | -                  | -  |
|                            | 50 µg (≥71 years)    | 10  | 10  | 3    | 30 | 7                | 70  | -                    | -  | -                  | -  |
|                            | 100 µg (≥71 years)   | 10  | 10  | 1    | 10 | 9                | 90  | -                    | -  | -                  | -  |
|                            | All Subjects         | 120 | 120 | 26   | 22 | 89               | 74  | 5                    | 4  | -                  | -  |
| Max Severity Post Baseline | 25 µg (18-55 years)  | 15  | 15  | 1    | 7  | 14               | 93  | -                    | -  | -                  | -  |
|                            | 50 µg (18-55 years)  | 15  | 15  | -    | -  | 12               | 80  | 3                    | 20 | -                  | -  |
|                            | 100 µg (18-55 years) | 15  | 15  | 3    | 20 | 12               | 80  | -                    | -  | -                  | -  |
|                            | 250 µg (18-55 years) | 15  | 15  | 1    | 7  | 11               | 73  | 3                    | 20 | -                  | -  |
|                            | 25 µg (56-70 years)  | 10  | 10  | -    | -  | 7                | 70  | 2                    | 20 | 1                  | 10 |
|                            | 50 µg (56-70 years)  | 10  | 10  | -    | -  | 10               | 100 | -                    | -  | -                  | -  |
|                            | 100 µg (56-70 years) | 10  | 10  | -    | -  | 9                | 90  | -                    | -  | 1                  | 10 |
|                            | 25 µg (≥71 years)    | 10  | 10  | -    | -  | 10               | 100 | -                    | -  | -                  | -  |
|                            | 50 µg (≥71 years)    | 10  | 10  | 2    | 20 | 8                | 80  | -                    | -  | -                  | -  |
|                            | 100 µg (≥71 years)   | 10  | 10  | -    | -  | 10               | 100 | -                    | -  | -                  | -  |
|                            | All Subjects         | 120 | 120 | 7    | 6  | 103              | 86  | 8                    | 7  | 2                  | 2  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7A:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group - Any Hematology Parameter** *(continued)*

|  |             |   |    | None |   | Mild/<br>Grade 1 |   | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|--|-------------|---|----|------|---|------------------|---|----------------------|---|--------------------|---|
| Timepoint  | Study Group | N | N* | n    | % | n                | % | n                    | % | n                  | % |
| Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.<br>N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit. |             |   |    |      |   |                  |   |                      |   |                    |   |

**TABLE 7B:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**White Blood Cells**

|                              |                      |     |     | None |     | Mild/<br>Grade 1<br>(Low) |    | Mild/<br>Grade 1<br>(High) |   | Moderate/<br>Grade 2<br>(Low) |   | Moderate/<br>Grade 2<br>(High) |   | Severe/<br>Grade 3<br>(Low) |   | Severe/<br>Grade 3<br>(High) |   |
|------------------------------|----------------------|-----|-----|------|-----|---------------------------|----|----------------------------|---|-------------------------------|---|--------------------------------|---|-----------------------------|---|------------------------------|---|
| Timepoint                    | Study Group          | N   | N*  | n    | %   | n                         | %  | n                          | % | n                             | % | n                              | % | n                           | % | n                            | % |
| Screening<br>(Day -42 to -1) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                              | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                              | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                              | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                              | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                              | All Subjects         | 120 | 120 | 120  | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
| Day 1, Baseline              | 25 µg (18-55 years)  | 15  | 15  | 13   | 87  | 2                         | 13 | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7B:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**White Blood Cells** (*continued*)

|                        |                      |     |     | None |     | Mild/<br>Grade 1<br>(Low) |    | Mild/<br>Grade 1<br>(High) |    | Moderate/<br>Grade 2<br>(Low) |   | Moderate/<br>Grade 2<br>(High) |   | Severe/<br>Grade 3<br>(Low) |   | Severe/<br>Grade 3<br>(High) |   |
|------------------------|----------------------|-----|-----|------|-----|---------------------------|----|----------------------------|----|-------------------------------|---|--------------------------------|---|-----------------------------|---|------------------------------|---|
| Timepoint              | Study Group          | N   | N*  | n    | %   | n                         | %  | n                          | %  | n                             | % | n                              | % | n                           | % | n                            | % |
|                        | 100 µg (18-55 years) | 15  | 15  | 13   | 87  | 2                         | 13 | -                          | -  | -                             | - | -                              | - | -                           | - | -                            | - |
|                        | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                         | -  | -                          | -  | -                             | - | -                              | - | -                           | - | -                            | - |
|                        | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                         | -  | -                          | -  | -                             | - | -                              | - | -                           | - | -                            | - |
|                        | 50 µg (56-70 years)  | 10  | 10  | 9    | 90  | -                         | -  | 1                          | 10 | -                             | - | -                              | - | -                           | - | -                            | - |
|                        | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                         | -  | -                          | -  | -                             | - | -                              | - | -                           | - | -                            | - |
|                        | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                         | -  | -                          | -  | -                             | - | -                              | - | -                           | - | -                            | - |
|                        | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                         | -  | -                          | -  | -                             | - | -                              | - | -                           | - | -                            | - |
|                        | 100 µg (≥71 years)   | 10  | 10  | 8    | 80  | 2                         | 20 | -                          | -  | -                             | - | -                              | - | -                           | - | -                            | - |
|                        | All Subjects         | 120 | 120 | 113  | 94  | 6                         | 5  | 1                          | 1  | -                             | - | -                              | - | -                           | - | -                            | - |
| Day 8<br>(Days 7 to 9) | 25 µg (18-55 years)  | 15  | 14  | 12   | 86  | 2                         | 14 | -                          | -  | -                             | - | -                              | - | -                           | - | -                            | - |
|                        | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                         | -  | -                          | -  | -                             | - | -                              | - | -                           | - | -                            | - |
|                        | 100 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                         | 7  | -                          | -  | -                             | - | -                              | - | -                           | - | -                            | - |
|                        | 250 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                         | 7  | -                          | -  | -                             | - | -                              | - | -                           | - | -                            | - |
|                        | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                         | -  | -                          | -  | -                             | - | -                              | - | -                           | - | -                            | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**TABLE 7B:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**White Blood Cells** (*continued*)

|                           |                      |     |     | None |     | Mild/<br>Grade 1<br>(Low) |    | Mild/<br>Grade 1<br>(High) |   | Moderate/<br>Grade 2<br>(Low) |   | Moderate/<br>Grade 2<br>(High) |   | Severe/<br>Grade 3<br>(Low) |   | Severe/<br>Grade 3<br>(High) |   |
|---------------------------|----------------------|-----|-----|------|-----|---------------------------|----|----------------------------|---|-------------------------------|---|--------------------------------|---|-----------------------------|---|------------------------------|---|
| Timepoint                 | Study Group          | N   | N*  | n    | %   | n                         | %  | n                          | % | n                             | % | n                              | % | n                           | % | n                            | % |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 9    | 90  | 1                         | 10 | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                           | All Subjects         | 120 | 119 | 114  | 96  | 5                         | 4  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
| Day 29<br>(Days 27 to 31) | 25 µg (18-55 years)  | 15  | 15  | 13   | 87  | 2                         | 13 | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                           | 100 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                         | 7  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                           | 250 µg (18-55 years) | 15  | 14  | 14   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7B:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**White Blood Cells** (*continued*)

|                               |                      |     |     | None |     | Mild/<br>Grade 1<br>(Low) |    | Mild/<br>Grade 1<br>(High) |   | Moderate/<br>Grade 2<br>(Low) |   | Moderate/<br>Grade 2<br>(High) |   | Severe/<br>Grade 3<br>(Low) |   | Severe/<br>Grade 3<br>(High) |   |
|-------------------------------|----------------------|-----|-----|------|-----|---------------------------|----|----------------------------|---|-------------------------------|---|--------------------------------|---|-----------------------------|---|------------------------------|---|
| Timepoint                     | Study Group          | N   | N*  | n    | %   | n                         | %  | n                          | % | n                             | % | n                              | % | n                           | % | n                            | % |
|                               | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                               | 100 µg (≥71 years)   | 10  | 10  | 8    | 80  | 2                         | 20 | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                               | All Subjects         | 120 | 119 | 114  | 96  | 5                         | 4  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
| Day 36<br>(Days 35 to 37)     | 25 µg (18-55 years)  | 15  | 15  | 13   | 87  | 2                         | 13 | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                               | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                               | 100 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                         | 7  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                               | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                               | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                               | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                               | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                               | 25 µg (≥71 years)    | 10  | 10  | 9    | 90  | 1                         | 10 | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                               | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                               | 100 µg (≥71 years)   | 10  | 10  | 7    | 70  | 3                         | 30 | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|                               | All Subjects         | 120 | 120 | 113  | 94  | 7                         | 6  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
| Max Severity<br>Post Baseline | 25 µg (18-55 years)  | 15  | 15  | 11   | 73  | 4                         | 27 | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7B:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**White Blood Cells** (*continued*)

|   |                      |     |     | None |     | Mild/<br>Grade 1<br>(Low) |    | Mild/<br>Grade 1<br>(High) |   | Moderate/<br>Grade 2<br>(Low) |   | Moderate/<br>Grade 2<br>(High) |   | Severe/<br>Grade 3<br>(Low) |   | Severe/<br>Grade 3<br>(High) |   |
|---|----------------------|-----|-----|------|-----|---------------------------|----|----------------------------|---|-------------------------------|---|--------------------------------|---|-----------------------------|---|------------------------------|---|
| Timepoint   | Study Group          | N   | N*  | n    | %   | n                         | %  | n                          | % | n                             | % | n                              | % | n                           | % | n                            | % |
|   | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|   | 100 µg (18-55 years) | 15  | 15  | 13   | 87  | 2                         | 13 | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|   | 250 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                         | 7  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|   | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|   | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|   | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|   | 25 µg (≥71 years)    | 10  | 10  | 9    | 90  | 1                         | 10 | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|   | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                         | -  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|   | 100 µg (≥71 years)   | 10  | 10  | 7    | 70  | 3                         | 30 | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
|   | All Subjects         | 120 | 120 | 109  | 91  | 11                        | 9  | -                          | - | -                             | - | -                              | - | -                           | - | -                            | - |
| <p>Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.</p> <p>N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.</p> |                      |     |     |      |     |                           |    |                            |   |                               |   |                                |   |                             |   |                              |   |

**TABLE 7C:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Hemoglobin**

| Timepoint                    | Study Group          | N   | N*  | None |     | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|------------------------------|----------------------|-----|-----|------|-----|------------------|----|----------------------|---|--------------------|---|
|                              |                      |     |     | n    | %   | n                | %  | n                    | % | n                  | % |
| Screening<br>(Day -42 to -1) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 14   | 93  | 1                | 7  | -                    | - | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                | 7  | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 25 µg (≥71 years)    | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | - |
|                              | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 100 µg (≥71 years)   | 10  | 10  | 8    | 80  | 2                | 20 | -                    | - | -                  | - |
|                              | All Subjects         | 120 | 120 | 115  | 96  | 5                | 4  | -                    | - | -                  | - |
| Day 1, Baseline              | 25 µg (18-55 years)  | 15  | 15  | 12   | 80  | 3                | 20 | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 12   | 80  | 3                | 20 | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                | 7  | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7C:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Hemoglobin** *(continued)*

|                           |                      |     |     | None |     | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |    | Severe/<br>Grade 3 |   |
|---------------------------|----------------------|-----|-----|------|-----|------------------|----|----------------------|----|--------------------|---|
| Timepoint                 | Study Group          | N   | N*  | n    | %   | n                | %  | n                    | %  | n                  | % |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -  | -                    | -  | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 9    | 90  | 1                | 10 | -                    | -  | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | -  | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 8    | 80  | 2                | 20 | -                    | -  | -                  | - |
|                           | All Subjects         | 120 | 120 | 110  | 92  | 10               | 8  | -                    | -  | -                  | - |
| Day 8<br>(Days 7 to 9)    | 25 µg (18-55 years)  | 15  | 14  | 5    | 36  | 9                | 64 | -                    | -  | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 1    | 7   | 13               | 87 | 1                    | 7  | -                  | - |
|                           | 100 µg (18-55 years) | 15  | 15  | 6    | 40  | 9                | 60 | -                    | -  | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 15  | 3    | 20  | 11               | 73 | 1                    | 7  | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 1    | 10  | 7                | 70 | 2                    | 20 | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 1    | 10  | 9                | 90 | -                    | -  | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 1    | 10  | 9                | 90 | -                    | -  | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 1    | 10  | 9                | 90 | -                    | -  | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 2    | 20  | 8                | 80 | -                    | -  | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 2    | 20  | 8                | 80 | -                    | -  | -                  | - |
|                           | All Subjects         | 120 | 119 | 23   | 19  | 92               | 77 | 4                    | 3  | -                  | - |
| Day 29<br>(Days 27 to 31) | 25 µg (18-55 years)  | 15  | 15  | 3    | 20  | 12               | 80 | -                    | -  | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 5    | 33  | 10               | 67 | -                    | -  | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7C:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Hemoglobin** *(continued)*

|                           |                      |     |     | None |    | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |    | Severe/<br>Grade 3 |    |
|---------------------------|----------------------|-----|-----|------|----|------------------|----|----------------------|----|--------------------|----|
| Timepoint                 | Study Group          | N   | N*  | n    | %  | n                | %  | n                    | %  | n                  | %  |
|                           | 100 µg (18-55 years) | 15  | 15  | 6    | 40 | 9                | 60 | -                    | -  | -                  | -  |
|                           | 250 µg (18-55 years) | 15  | 14  | 4    | 29 | 10               | 71 | -                    | -  | -                  | -  |
|                           | 25 µg (56-70 years)  | 10  | 10  | 1    | 10 | 7                | 70 | 1                    | 10 | 1                  | 10 |
|                           | 50 µg (56-70 years)  | 10  | 10  | 1    | 10 | 9                | 90 | -                    | -  | -                  | -  |
|                           | 100 µg (56-70 years) | 10  | 10  | 1    | 10 | 9                | 90 | -                    | -  | -                  | -  |
|                           | 25 µg (≥71 years)    | 10  | 10  | 6    | 60 | 4                | 40 | -                    | -  | -                  | -  |
|                           | 50 µg (≥71 years)    | 10  | 10  | 4    | 40 | 6                | 60 | -                    | -  | -                  | -  |
|                           | 100 µg (≥71 years)   | 10  | 10  | 3    | 30 | 7                | 70 | -                    | -  | -                  | -  |
|                           | All Subjects         | 120 | 119 | 34   | 29 | 83               | 70 | 1                    | 1  | 1                  | 1  |
| Day 36<br>(Days 35 to 37) | 25 µg (18-55 years)  | 15  | 15  | 7    | 47 | 8                | 53 | -                    | -  | -                  | -  |
|                           | 50 µg (18-55 years)  | 15  | 15  | 2    | 13 | 11               | 73 | 2                    | 13 | -                  | -  |
|                           | 100 µg (18-55 years) | 15  | 15  | 4    | 27 | 11               | 73 | -                    | -  | -                  | -  |
|                           | 250 µg (18-55 years) | 15  | 15  | 2    | 13 | 11               | 73 | 2                    | 13 | -                  | -  |
|                           | 25 µg (56-70 years)  | 10  | 10  | 3    | 30 | 7                | 70 | -                    | -  | -                  | -  |
|                           | 50 µg (56-70 years)  | 10  | 10  | 1    | 10 | 9                | 90 | -                    | -  | -                  | -  |
|                           | 100 µg (56-70 years) | 10  | 10  | -    | -  | 9                | 90 | 1                    | 10 | -                  | -  |
|                           | 25 µg (≥71 years)    | 10  | 10  | 4    | 40 | 6                | 60 | -                    | -  | -                  | -  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7C:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Hemoglobin** *(continued)*

|   |                      |     |     | None |    | Mild/<br>Grade 1 |     | Moderate/<br>Grade 2 |    | Severe/<br>Grade 3 |    |
|---|----------------------|-----|-----|------|----|------------------|-----|----------------------|----|--------------------|----|
| Timepoint   | Study Group          | N   | N*  | n    | %  | n                | %   | n                    | %  | n                  | %  |
| Max Severity Post Baseline  | 50 µg (≥71 years)    | 10  | 10  | 3    | 30 | 7                | 70  | -                    | -  | -                  | -  |
|   | 100 µg (≥71 years)   | 10  | 10  | 2    | 20 | 8                | 80  | -                    | -  | -                  | -  |
|   | All Subjects         | 120 | 120 | 28   | 23 | 87               | 73  | 5                    | 4  | -                  | -  |
|   | 25 µg (18-55 years)  | 15  | 15  | 1    | 7  | 14               | 93  | -                    | -  | -                  | -  |
|   | 50 µg (18-55 years)  | 15  | 15  | -    | -  | 12               | 80  | 3                    | 20 | -                  | -  |
|   | 100 µg (18-55 years) | 15  | 15  | 3    | 20 | 12               | 80  | -                    | -  | -                  | -  |
|   | 250 µg (18-55 years) | 15  | 15  | 2    | 13 | 10               | 67  | 3                    | 20 | -                  | -  |
|   | 25 µg (56-70 years)  | 10  | 10  | -    | -  | 7                | 70  | 2                    | 20 | 1                  | 10 |
|   | 50 µg (56-70 years)  | 10  | 10  | -    | -  | 10               | 100 | -                    | -  | -                  | -  |
|   | 100 µg (56-70 years) | 10  | 10  | -    | -  | 9                | 90  | -                    | -  | 1                  | 10 |
|   | 25 µg (≥71 years)    | 10  | 10  | 1    | 10 | 9                | 90  | -                    | -  | -                  | -  |
|   | 50 µg (≥71 years)    | 10  | 10  | 2    | 20 | 8                | 80  | -                    | -  | -                  | -  |
|   | 100 µg (≥71 years)   | 10  | 10  | -    | -  | 10               | 100 | -                    | -  | -                  | -  |
|   | All Subjects         | 120 | 120 | 9    | 8  | 101              | 84  | 8                    | 7  | 2                  | 2  |
| <p>Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.</p> <p>N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.</p> |                      |     |     |      |    |                  |     |                      |    |                    |    |

**TABLE 7D:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group – Platelets**

| Timepoint                    | Study Group          | N   | N*  | None |     | Mild/<br>Grade 1 |   | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|------------------------------|----------------------|-----|-----|------|-----|------------------|---|----------------------|---|--------------------|---|
|                              |                      |     |     | n    | %   | n                | % | n                    | % | n                  | % |
| Screening<br>(Day -42 to -1) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | All Subjects         | 120 | 120 | 120  | 100 | -                | - | -                    | - | -                  | - |
| Day 1, Baseline              | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**TABLE 7D:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Platelets** (*continued*)

|                           |                      |     |     | None |     | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |    | Severe/<br>Grade 3 |   |
|---------------------------|----------------------|-----|-----|------|-----|------------------|----|----------------------|----|--------------------|---|
| Timepoint                 | Study Group          | N   | N*  | n    | %   | n                | %  | n                    | %  | n                  | % |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -  | -                    | -  | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | -  | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | -  | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 9    | 90  | -                | -  | 1                    | 10 | -                  | - |
|                           | All Subjects         | 120 | 120 | 119  | 99  | -                | -  | 1                    | 1  | -                  | - |
| Day 8<br>(Days 7 to 9)    | 25 µg (18-55 years)  | 15  | 14  | 14   | 100 | -                | -  | -                    | -  | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | -  | -                  | - |
|                           | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | -  | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | -  | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | -  | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | -  | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -  | -                    | -  | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | -  | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | -  | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 9    | 90  | 1                | 10 | -                    | -  | -                  | - |
|                           | All Subjects         | 120 | 119 | 118  | 99  | 1                | 1  | -                    | -  | -                  | - |
| Day 29<br>(Days 27 to 31) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | -  | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | -  | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7D:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Platelets** (*continued*)

|                           |                      |     |     | None |     | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---------------------------|----------------------|-----|-----|------|-----|------------------|----|----------------------|---|--------------------|---|
| Timepoint                 | Study Group          | N   | N*  | n    | %   | n                | %  | n                    | % | n                  | % |
|                           | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 14  | 14   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 9    | 90  | -                | -  | -                    | - | -                  | - |
|                           | All Subjects         | 120 | 119 | 117  | 98  | 1                | 1  | -                    | - | -                  | - |
| Day 36<br>(Days 35 to 37) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7D:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Platelets** *(continued)*

|   |                      |     |     | None |     | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---|----------------------|-----|-----|------|-----|------------------|----|----------------------|---|--------------------|---|
| Timepoint   | Study Group          | N   | N*  | n    | %   | n                | %  | n                    | % | n                  | % |
| Max Severity Post Baseline  | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | All Subjects         | 120 | 120 | 120  | 100 | -                | -  | -                    | - | -                  | - |
|   | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|   | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|   | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|   | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|   | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | 25 µg (≥71 years)    | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | - |
|   | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | 100 µg (≥71 years)   | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | - |
|   | All Subjects         | 120 | 120 | 118  | 98  | 2                | 2  | -                    | - | -                  | - |
| <p>Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.</p> <p>N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.</p> |                      |     |     |      |     |                  |    |                      |   |                    |   |

**TABLE 7E:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Any Chemistry Parameter**

| Timepoint                    | Study Group          | N   | N*  | None |     | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|------------------------------|----------------------|-----|-----|------|-----|------------------|----|----------------------|---|--------------------|---|
|                              |                      |     |     | n    | %   | n                | %  | n                    | % | n                  | % |
| Screening<br>(Day -42 to -1) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | All Subjects         | 120 | 120 | 120  | 100 | -                | -  | -                    | - | -                  | - |
| Day 1, Baseline              | 25 µg (18-55 years)  | 15  | 15  | 14   | 93  | 1                | 7  | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 14   | 93  | -                | -  | 1                    | 7 | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                | 7  | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7E:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Any Chemistry Parameter** *(continued)*

|                           |                      |     |     | None |     | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |    |
|---------------------------|----------------------|-----|-----|------|-----|------------------|----|----------------------|---|--------------------|----|
| Timepoint                 | Study Group          | N   | N*  | n    | %   | n                | %  | n                    | % | n                  | %  |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|                           | 50 µg (≥71 years)    | 10  | 10  | 9    | 90  | -                | -  | -                    | - | 1                  | 10 |
|                           | 100 µg (≥71 years)   | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | -  |
|                           | All Subjects         | 120 | 120 | 114  | 95  | 4                | 3  | 1                    | 1 | 1                  | 1  |
| Day 8<br>(Days 7 to 9)    | 25 µg (18-55 years)  | 15  | 14  | 12   | 86  | 2                | 14 | -                    | - | -                  | -  |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | -  |
|                           | 100 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                | 7  | -                    | - | -                  | -  |
|                           | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | -  |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|                           | 25 µg (≥71 years)    | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | -  |
|                           | 50 µg (≥71 years)    | 10  | 10  | 9    | 90  | -                | -  | -                    | - | 1                  | 10 |
|                           | 100 µg (≥71 years)   | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | -  |
|                           | All Subjects         | 120 | 119 | 113  | 95  | 5                | 4  | -                    | - | 1                  | 1  |
| Day 29<br>(Days 27 to 31) | 25 µg (18-55 years)  | 15  | 15  | 14   | 93  | -                | -  | 1                    | 7 | -                  | -  |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | -  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7E:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Any Chemistry Parameter** *(continued)*

|                           |                      |     |     | None |     | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---------------------------|----------------------|-----|-----|------|-----|------------------|----|----------------------|---|--------------------|---|
| Timepoint                 | Study Group          | N   | N*  | n    | %   | n                | %  | n                    | % | n                  | % |
|                           | 100 µg (18-55 years) | 15  | 15  | 12   | 80  | 3                | 20 | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 14  | 13   | 93  | 1                | 7  | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | All Subjects         | 120 | 119 | 113  | 95  | 5                | 4  | 1                    | 1 | -                  | - |
| Day 36<br>(Days 35 to 37) | 25 µg (18-55 years)  | 15  | 15  | 13   | 87  | 2                | 13 | -                    | - | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                | 7  | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 15  | 14   | 93  | -                | -  | 1                    | 7 | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7E:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Any Chemistry Parameter** *(continued)*

|   |                      |     |     | None |     | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |    |
|---|----------------------|-----|-----|------|-----|------------------|----|----------------------|---|--------------------|----|
| Timepoint   | Study Group          | N   | N*  | n    | %   | n                | %  | n                    | % | n                  | %  |
| Max Severity Post Baseline  | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|   | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|   | All Subjects         | 120 | 120 | 115  | 96  | 4                | 3  | 1                    | 1 | -                  | -  |
|   | 25 µg (18-55 years)  | 15  | 15  | 12   | 80  | 2                | 13 | 1                    | 7 | -                  | -  |
|   | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | -  |
|   | 100 µg (18-55 years) | 15  | 15  | 11   | 73  | 4                | 27 | -                    | - | -                  | -  |
|   | 250 µg (18-55 years) | 15  | 15  | 13   | 87  | 1                | 7  | -                    | - | 1                  | 7  |
|   | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|   | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|   | 100 µg (56-70 years) | 10  | 10  | 8    | 80  | 2                | 20 | -                    | - | -                  | -  |
|   | 25 µg (≥71 years)    | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | -  |
|   | 50 µg (≥71 years)    | 10  | 10  | 9    | 90  | -                | -  | -                    | - | 1                  | 10 |
|   | 100 µg (≥71 years)   | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | -  |
|   | All Subjects         | 120 | 120 | 106  | 88  | 11               | 9  | 1                    | 1 | 2                  | 2  |
| <p>Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.</p> <p>N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.</p> |                      |     |     |      |     |                  |    |                      |   |                    |    |

**TABLE 7F:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Alanine Aminotransferase**

| Timepoint                    | Study Group          | N   | N*  | None |     | Mild/<br>Grade 1 |   | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|------------------------------|----------------------|-----|-----|------|-----|------------------|---|----------------------|---|--------------------|---|
|                              |                      |     |     | n    | %   | n                | % | n                    | % | n                  | % |
| Screening<br>(Day -42 to -1) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | All Subjects         | 120 | 120 | 120  | 100 | -                | - | -                    | - | -                  | - |
| Day 1, Baseline              | 25 µg (18-55 years)  | 15  | 15  | 14   | 93  | 1                | 7 | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                | 7 | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**TABLE 7F:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Alanine Aminotransferase** (*continued*)

|                           |                      |     |     | None |     | Mild/<br>Grade 1 |   | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---------------------------|----------------------|-----|-----|------|-----|------------------|---|----------------------|---|--------------------|---|
| Timepoint                 | Study Group          | N   | N*  | n    | %   | n                | % | n                    | % | n                  | % |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | All Subjects         | 120 | 120 | 118  | 98  | 2                | 2 | -                    | - | -                  | - |
| Day 8<br>(Days 7 to 9)    | 25 µg (18-55 years)  | 15  | 14  | 13   | 93  | 1                | 7 | -                    | - | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                | 7 | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | All Subjects         | 120 | 119 | 117  | 98  | 2                | 2 | -                    | - | -                  | - |
| Day 29<br>(Days 27 to 31) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7F:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Alanine Aminotransferase** *(continued)*

|                           |                      |     |     | None |     | Mild/<br>Grade 1 |   | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---------------------------|----------------------|-----|-----|------|-----|------------------|---|----------------------|---|--------------------|---|
| Timepoint                 | Study Group          | N   | N*  | n    | %   | n                | % | n                    | % | n                  | % |
|                           | 100 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                | 7 | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 14  | 14   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | All Subjects         | 120 | 119 | 118  | 99  | 1                | 1 | -                    | - | -                  | - |
| Day 36<br>(Days 35 to 37) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7F:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Alanine Aminotransferase** (*continued*)

|   |                      |     |     | None |     | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---|----------------------|-----|-----|------|-----|------------------|----|----------------------|---|--------------------|---|
| Timepoint   | Study Group          | N   | N*  | n    | %   | n                | %  | n                    | % | n                  | % |
| Max Severity Post Baseline  | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | All Subjects         | 120 | 120 | 120  | 100 | -                | -  | -                    | - | -                  | - |
|   | 25 µg (18-55 years)  | 15  | 15  | 14   | 93  | 1                | 7  | -                    | - | -                  | - |
|   | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|   | 100 µg (18-55 years) | 15  | 15  | 13   | 87  | 2                | 13 | -                    | - | -                  | - |
|   | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|   | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | All Subjects         | 120 | 120 | 117  | 98  | 3                | 3  | -                    | - | -                  | - |
| <p>Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.</p> <p>N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.</p> |                      |     |     |      |     |                  |    |                      |   |                    |   |

**TABLE 7G:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Aspartate Aminotransferase**

| Timepoint                    | Study Group          | N   | N*  | None |     | Mild/<br>Grade 1 |   | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|------------------------------|----------------------|-----|-----|------|-----|------------------|---|----------------------|---|--------------------|---|
|                              |                      |     |     | n    | %   | n                | % | n                    | % | n                  | % |
| Screening<br>(Day -42 to -1) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | All Subjects         | 120 | 120 | 120  | 100 | -                | - | -                    | - | -                  | - |
| Day 1, Baseline              | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7G:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Aspartate Aminotransferase** *(continued)*

|                           |                      |     |     | None |     | Mild/<br>Grade 1 |   | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---------------------------|----------------------|-----|-----|------|-----|------------------|---|----------------------|---|--------------------|---|
| Timepoint                 | Study Group          | N   | N*  | n    | %   | n                | % | n                    | % | n                  | % |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | All Subjects         | 120 | 120 | 120  | 100 | -                | - | -                    | - | -                  | - |
| Day 8<br>(Days 7 to 9)    | 25 µg (18-55 years)  | 15  | 14  | 14   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | All Subjects         | 120 | 119 | 119  | 100 | -                | - | -                    | - | -                  | - |
| Day 29<br>(Days 27 to 31) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7G:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Aspartate Aminotransferase** *(continued)*

|                           |                      |     |     | None |     | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---------------------------|----------------------|-----|-----|------|-----|------------------|----|----------------------|---|--------------------|---|
| Timepoint                 | Study Group          | N   | N*  | n    | %   | n                | %  | n                    | % | n                  | % |
|                           | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 14  | 14   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | All Subjects         | 120 | 119 | 118  | 99  | 1                | 1  | -                    | - | -                  | - |
| Day 36<br>(Days 35 to 37) | 25 µg (18-55 years)  | 15  | 15  | 14   | 93  | 1                | 7  | -                    | - | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7G:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Aspartate Aminotransferase** *(continued)*

|   |                      |     |     | None |     | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---|----------------------|-----|-----|------|-----|------------------|----|----------------------|---|--------------------|---|
| Timepoint   | Study Group          | N   | N*  | n    | %   | n                | %  | n                    | % | n                  | % |
| Max Severity Post Baseline  | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | All Subjects         | 120 | 120 | 119  | 99  | 1                | 1  | -                    | - | -                  | - |
|   | 25 µg (18-55 years)  | 15  | 15  | 14   | 93  | 1                | 7  | -                    | - | -                  | - |
|   | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|   | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|   | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|   | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | 100 µg (56-70 years) | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | - |
|   | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|   | All Subjects         | 120 | 120 | 118  | 98  | 2                | 2  | -                    | - | -                  | - |
| <p>Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.</p> <p>N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.</p> |                      |     |     |      |     |                  |    |                      |   |                    |   |

**TABLE 7H:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Alkaline Phosphatase**

| Timepoint                    | Study Group          | N   | N*  | None |     | Mild/<br>Grade 1 |   | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|------------------------------|----------------------|-----|-----|------|-----|------------------|---|----------------------|---|--------------------|---|
|                              |                      |     |     | n    | %   | n                | % | n                    | % | n                  | % |
| Screening<br>(Day -42 to -1) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | All Subjects         | 120 | 120 | 120  | 100 | -                | - | -                    | - | -                  | - |
| Day 1, Baseline              | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**TABLE 7H:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Alkaline Phosphatase** *(continued)*

|                           |                      |     |     | None |     | Mild/<br>Grade 1 |   | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---------------------------|----------------------|-----|-----|------|-----|------------------|---|----------------------|---|--------------------|---|
| Timepoint                 | Study Group          | N   | N*  | n    | %   | n                | % | n                    | % | n                  | % |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | All Subjects         | 120 | 120 | 120  | 100 | -                | - | -                    | - | -                  | - |
| Day 8<br>(Days 7 to 9)    | 25 µg (18-55 years)  | 15  | 14  | 14   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | All Subjects         | 120 | 119 | 119  | 100 | -                | - | -                    | - | -                  | - |
| Day 29<br>(Days 27 to 31) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7H:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Alkaline Phosphatase** *(continued)*

|                           |                      |     |     | None |     | Mild/<br>Grade 1 |   | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---------------------------|----------------------|-----|-----|------|-----|------------------|---|----------------------|---|--------------------|---|
| Timepoint                 | Study Group          | N   | N*  | n    | %   | n                | % | n                    | % | n                  | % |
|                           | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 14  | 14   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | All Subjects         | 120 | 119 | 119  | 100 | -                | - | -                    | - | -                  | - |
| Day 36<br>(Days 35 to 37) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7H:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Alkaline Phosphatase** *(continued)*

|   |                      |     |     | None |     | Mild/<br>Grade 1 |   | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---|----------------------|-----|-----|------|-----|------------------|---|----------------------|---|--------------------|---|
| Timepoint   | Study Group          | N   | N*  | n    | %   | n                | % | n                    | % | n                  | % |
| Max Severity Post Baseline  | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | All Subjects         | 120 | 120 | 120  | 100 | -                | - | -                    | - | -                  | - |
|   | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|   | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|   | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|   | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|   | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | All Subjects         | 120 | 120 | 120  | 100 | -                | - | -                    | - | -                  | - |
| <p>Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.</p> <p>N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.</p> |                      |     |     |      |     |                  |   |                      |   |                    |   |

**TABLE 7I:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Total Bilirubin**

| Timepoint                    | Study Group          | N   | N*  | None |     | Mild/<br>Grade 1 |   | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|------------------------------|----------------------|-----|-----|------|-----|------------------|---|----------------------|---|--------------------|---|
|                              |                      |     |     | n    | %   | n                | % | n                    | % | n                  | % |
| Screening<br>(Day -42 to -1) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | All Subjects         | 120 | 120 | 120  | 100 | -                | - | -                    | - | -                  | - |
| Day 1, Baseline              | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7I:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Total Bilirubin** *(continued)*

|                           |                      |     |     | None |     | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---------------------------|----------------------|-----|-----|------|-----|------------------|----|----------------------|---|--------------------|---|
| Timepoint                 | Study Group          | N   | N*  | n    | %   | n                | %  | n                    | % | n                  | % |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | - |
|                           | All Subjects         | 120 | 120 | 119  | 99  | 1                | 1  | -                    | - | -                  | - |
| Day 8<br>(Days 7 to 9)    | 25 µg (18-55 years)  | 15  | 14  | 13   | 93  | 1                | 7  | -                    | - | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | All Subjects         | 120 | 119 | 118  | 99  | 1                | 1  | -                    | - | -                  | - |
| Day 29<br>(Days 27 to 31) | 25 µg (18-55 years)  | 15  | 15  | 14   | 93  | -                | -  | 1                    | 7 | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7I:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Total Bilirubin** *(continued)*

|                           |                      |     |     | None |     | Mild/<br>Grade 1 |   | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---------------------------|----------------------|-----|-----|------|-----|------------------|---|----------------------|---|--------------------|---|
| Timepoint                 | Study Group          | N   | N*  | n    | %   | n                | % | n                    | % | n                  | % |
|                           | 100 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                | 7 | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 14  | 13   | 93  | 1                | 7 | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | All Subjects         | 120 | 119 | 116  | 97  | 2                | 2 | 1                    | 1 | -                  | - |
| Day 36<br>(Days 35 to 37) | 25 µg (18-55 years)  | 15  | 15  | 14   | 93  | 1                | 7 | -                    | - | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7I:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Total Bilirubin** *(continued)*

|   |                      |     |     | None |     | Mild/<br>Grade 1 |   | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---|----------------------|-----|-----|------|-----|------------------|---|----------------------|---|--------------------|---|
| Timepoint   | Study Group          | N   | N*  | n    | %   | n                | % | n                    | % | n                  | % |
| Max Severity Post Baseline  | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | All Subjects         | 120 | 120 | 119  | 99  | 1                | 1 | -                    | - | -                  | - |
|   | 25 µg (18-55 years)  | 15  | 15  | 14   | 93  | -                | - | 1                    | 7 | -                  | - |
|   | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|   | 100 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                | 7 | -                    | - | -                  | - |
|   | 250 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                | 7 | -                    | - | -                  | - |
|   | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | All Subjects         | 120 | 120 | 117  | 98  | 2                | 2 | 1                    | 1 | -                  | - |
| <p>Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.</p> <p>N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.</p> |                      |     |     |      |     |                  |   |                      |   |                    |   |

**TABLE 7J:**  
**Laboratory Results by Parameter, Severity, and Study Day**  
**Serum Creatinine**

| Timepoint                    | Study Group          | N   | N*  | None |     | Mild/<br>Grade 1 |   | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|------------------------------|----------------------|-----|-----|------|-----|------------------|---|----------------------|---|--------------------|---|
|                              |                      |     |     | n    | %   | n                | % | n                    | % | n                  | % |
| Screening<br>(Day -42 to -1) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | All Subjects         | 120 | 120 | 120  | 100 | -                | - | -                    | - | -                  | - |
| Day 1, Baseline              | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**TABLE 7J:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Serum Creatinine** (*continued*)

|                           |                      |     |     | None |     | Mild/<br>Grade 1 |   | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---------------------------|----------------------|-----|-----|------|-----|------------------|---|----------------------|---|--------------------|---|
| Timepoint                 | Study Group          | N   | N*  | n    | %   | n                | % | n                    | % | n                  | % |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | All Subjects         | 120 | 120 | 120  | 100 | -                | - | -                    | - | -                  | - |
| Day 8<br>(Days 7 to 9)    | 25 µg (18-55 years)  | 15  | 14  | 14   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | All Subjects         | 120 | 119 | 119  | 100 | -                | - | -                    | - | -                  | - |
| Day 29<br>(Days 27 to 31) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7J:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Serum Creatinine** *(continued)*

|                           |                      |     |     | None |     | Mild/<br>Grade 1 |   | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---------------------------|----------------------|-----|-----|------|-----|------------------|---|----------------------|---|--------------------|---|
| Timepoint                 | Study Group          | N   | N*  | n    | %   | n                | % | n                    | % | n                  | % |
|                           | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 14  | 14   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | All Subjects         | 120 | 119 | 119  | 100 | -                | - | -                    | - | -                  | - |
| Day 36<br>(Days 35 to 37) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7J:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Serum Creatinine** (*continued*)

|   |                      |     |     | None |     | Mild/<br>Grade 1 |   | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---|----------------------|-----|-----|------|-----|------------------|---|----------------------|---|--------------------|---|
| Timepoint   | Study Group          | N   | N*  | n    | %   | n                | % | n                    | % | n                  | % |
| Max Severity Post Baseline  | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | All Subjects         | 120 | 120 | 120  | 100 | -                | - | -                    | - | -                  | - |
|   | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|   | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|   | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|   | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | - | -                    | - | -                  | - |
|   | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | - | -                    | - | -                  | - |
|   | All Subjects         | 120 | 120 | 120  | 100 | -                | - | -                    | - | -                  | - |
| <p>Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.</p> <p>N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.</p> |                      |     |     |      |     |                  |   |                      |   |                    |   |

**TABLE 7K:**  
**Laboratory Results by Parameter, Severity, and Study Day**  
**Serum Lipase**

| Timepoint                    | Study Group          | N   | N*  | None |     | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|------------------------------|----------------------|-----|-----|------|-----|------------------|----|----------------------|---|--------------------|---|
|                              |                      |     |     | n    | %   | n                | %  | n                    | % | n                  | % |
| Screening<br>(Day -42 to -1) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                              | All Subjects         | 120 | 120 | 120  | 100 | -                | -  | -                    | - | -                  | - |
| Day 1, Baseline              | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 50 µg (18-55 years)  | 15  | 15  | 14   | 93  | -                | -  | 1                    | 7 | -                  | - |
|                              | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                              | 25 µg (56-70 years)  | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | - |
|                              | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7K:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Serum Lipase** *(continued)*

|                           |                      |     |     | None |     | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |    |
|---------------------------|----------------------|-----|-----|------|-----|------------------|----|----------------------|---|--------------------|----|
| Timepoint                 | Study Group          | N   | N*  | n    | %   | n                | %  | n                    | % | n                  | %  |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|                           | 50 µg (≥71 years)    | 10  | 10  | 9    | 90  | -                | -  | -                    | - | 1                  | 10 |
|                           | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|                           | All Subjects         | 120 | 120 | 117  | 98  | 1                | 1  | 1                    | 1 | 1                  | 1  |
| Day 8<br>(Days 7 to 9)    | 25 µg (18-55 years)  | 15  | 14  | 14   | 100 | -                | -  | -                    | - | -                  | -  |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | -  |
|                           | 100 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | -  |
|                           | 250 µg (18-55 years) | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | -  |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|                           | 25 µg (≥71 years)    | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | -  |
|                           | 50 µg (≥71 years)    | 10  | 10  | 9    | 90  | -                | -  | -                    | - | 1                  | 10 |
|                           | 100 µg (≥71 years)   | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | -  |
|                           | All Subjects         | 120 | 119 | 116  | 97  | 2                | 2  | -                    | - | 1                  | 1  |
| Day 29<br>(Days 27 to 31) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | -  |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | -  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7K:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Serum Lipase** *(continued)*

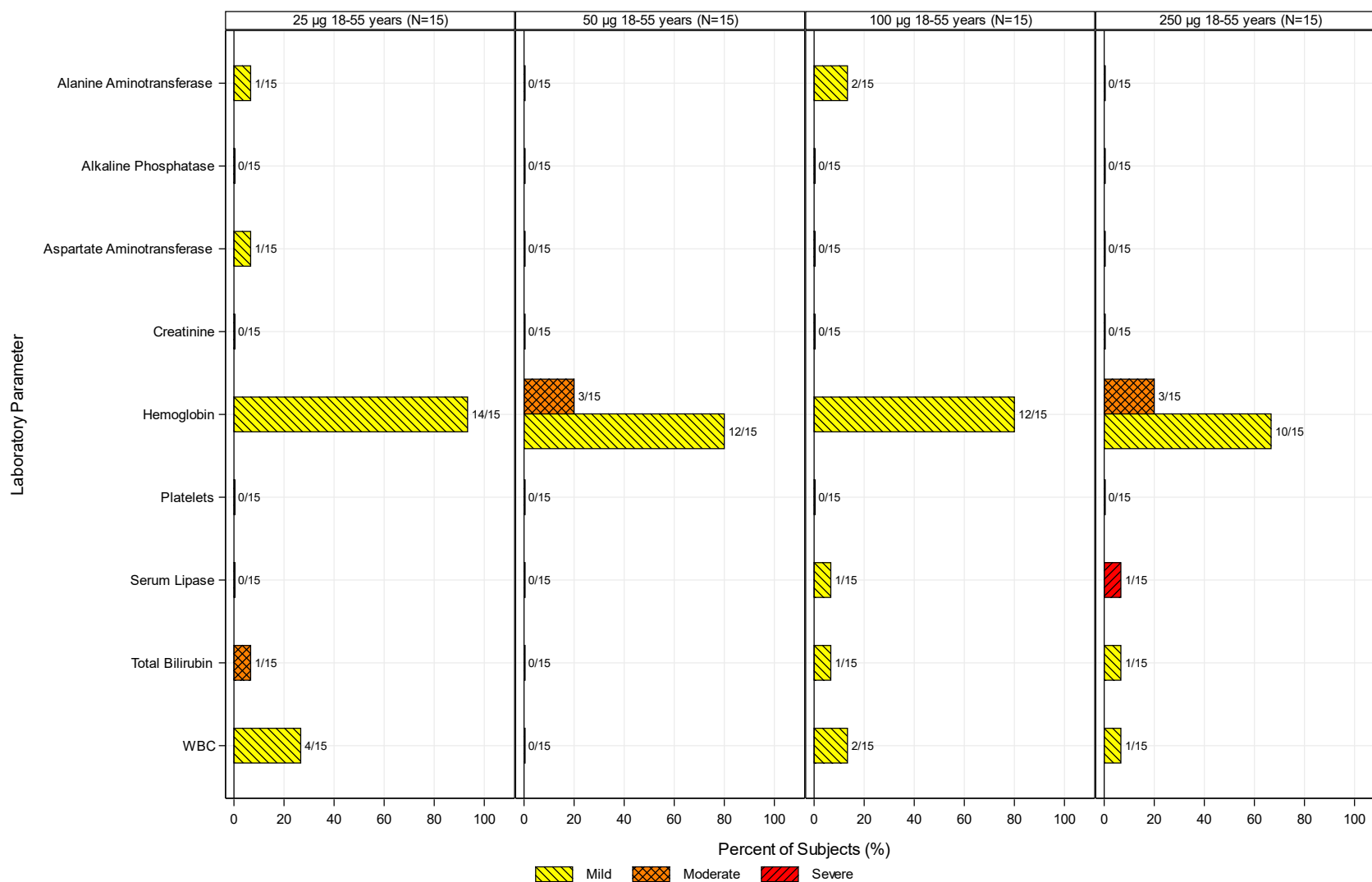
|                           |                      |     |     | None |     | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |   |
|---------------------------|----------------------|-----|-----|------|-----|------------------|----|----------------------|---|--------------------|---|
| Timepoint                 | Study Group          | N   | N*  | n    | %   | n                | %  | n                    | % | n                  | % |
|                           | 100 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                | 7  | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 14  | 14   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | All Subjects         | 120 | 119 | 118  | 99  | 1                | 1  | -                    | - | -                  | - |
| Day 36<br>(Days 35 to 37) | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                | 7  | -                    | - | -                  | - |
|                           | 250 µg (18-55 years) | 15  | 15  | 14   | 93  | -                | -  | 1                    | 7 | -                  | - |
|                           | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |
|                           | 100 µg (56-70 years) | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | - |
|                           | 25 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | - |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 7K:**  
**Laboratory Results by Parameter, Severity, Study Day, and Vaccination Group –**  
**Serum Lipase** *(continued)*

|   |                      |     |     | None |     | Mild/<br>Grade 1 |    | Moderate/<br>Grade 2 |   | Severe/<br>Grade 3 |    |
|---|----------------------|-----|-----|------|-----|------------------|----|----------------------|---|--------------------|----|
| Timepoint   | Study Group          | N   | N*  | n    | %   | n                | %  | n                    | % | n                  | %  |
| Max Severity Post Baseline  | 50 µg (≥71 years)    | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|   | 100 µg (≥71 years)   | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|   | All Subjects         | 120 | 120 | 117  | 98  | 2                | 2  | 1                    | 1 | -                  | -  |
|   | 25 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | -  |
|   | 50 µg (18-55 years)  | 15  | 15  | 15   | 100 | -                | -  | -                    | - | -                  | -  |
|   | 100 µg (18-55 years) | 15  | 15  | 14   | 93  | 1                | 7  | -                    | - | -                  | -  |
|   | 250 µg (18-55 years) | 15  | 15  | 14   | 93  | -                | -  | -                    | - | 1                  | 7  |
|   | 25 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|   | 50 µg (56-70 years)  | 10  | 10  | 10   | 100 | -                | -  | -                    | - | -                  | -  |
|   | 100 µg (56-70 years) | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | -  |
|   | 25 µg (≥71 years)    | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | -  |
|   | 50 µg (≥71 years)    | 10  | 10  | 9    | 90  | -                | -  | -                    | - | 1                  | 10 |
|   | 100 µg (≥71 years)   | 10  | 10  | 9    | 90  | 1                | 10 | -                    | - | -                  | -  |
|   | All Subjects         | 120 | 120 | 114  | 95  | 4                | 3  | -                    | - | 2                  | 2  |
| <p>Note: The “Max Severity Post Baseline” rows indicate the maximum severity experienced by each subject at any time point post baseline, including unscheduled assessments.</p> <p>N = Number of subjects enrolled and vaccinated; N* = Number of subjects that completed the visit.</p> |                      |     |     |      |     |                  |    |                      |   |                    |    |

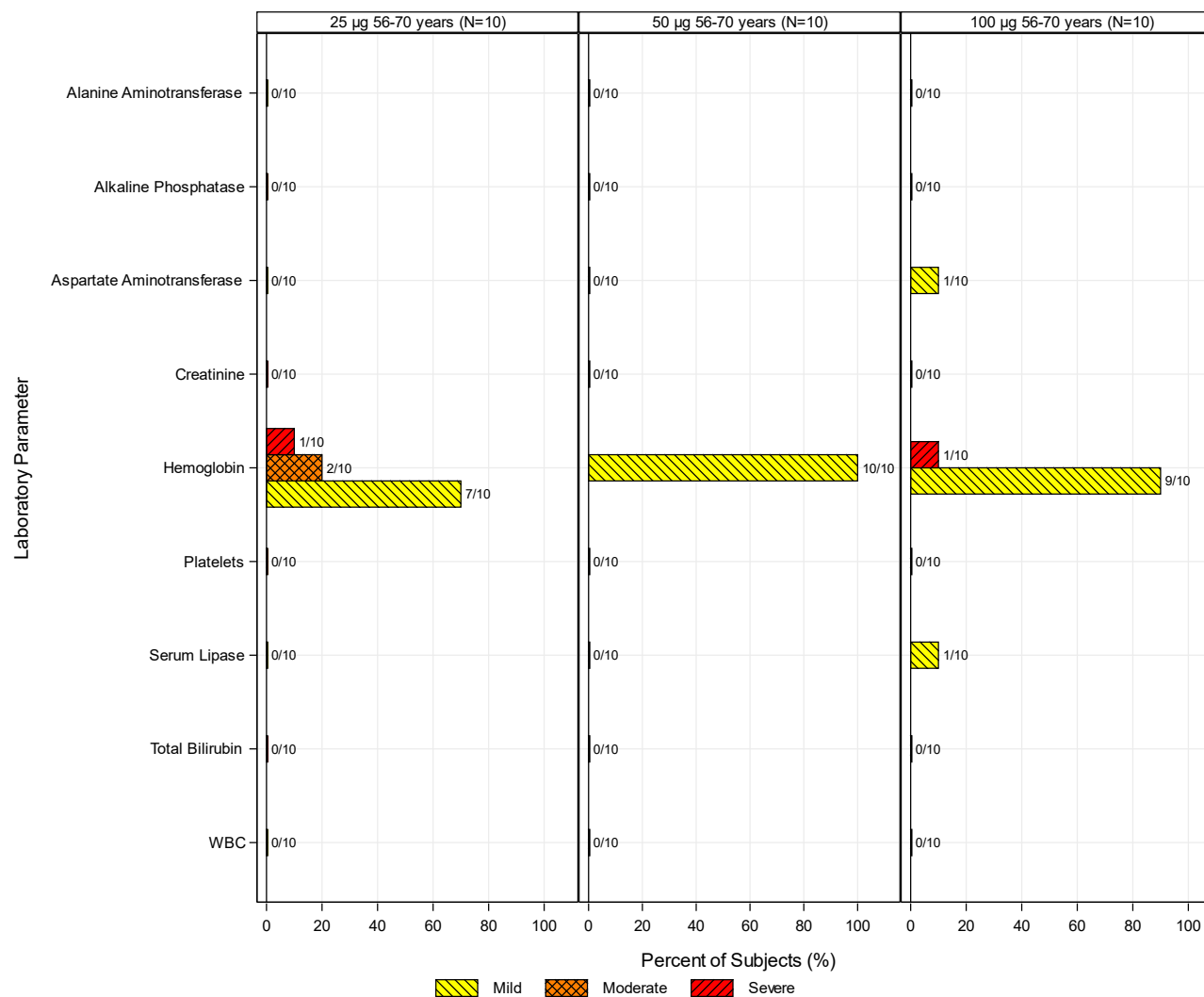
**FIGURE 5A:**  
**Clinical Laboratory Results by Severity and Vaccination Group 18-55 Years of Age**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

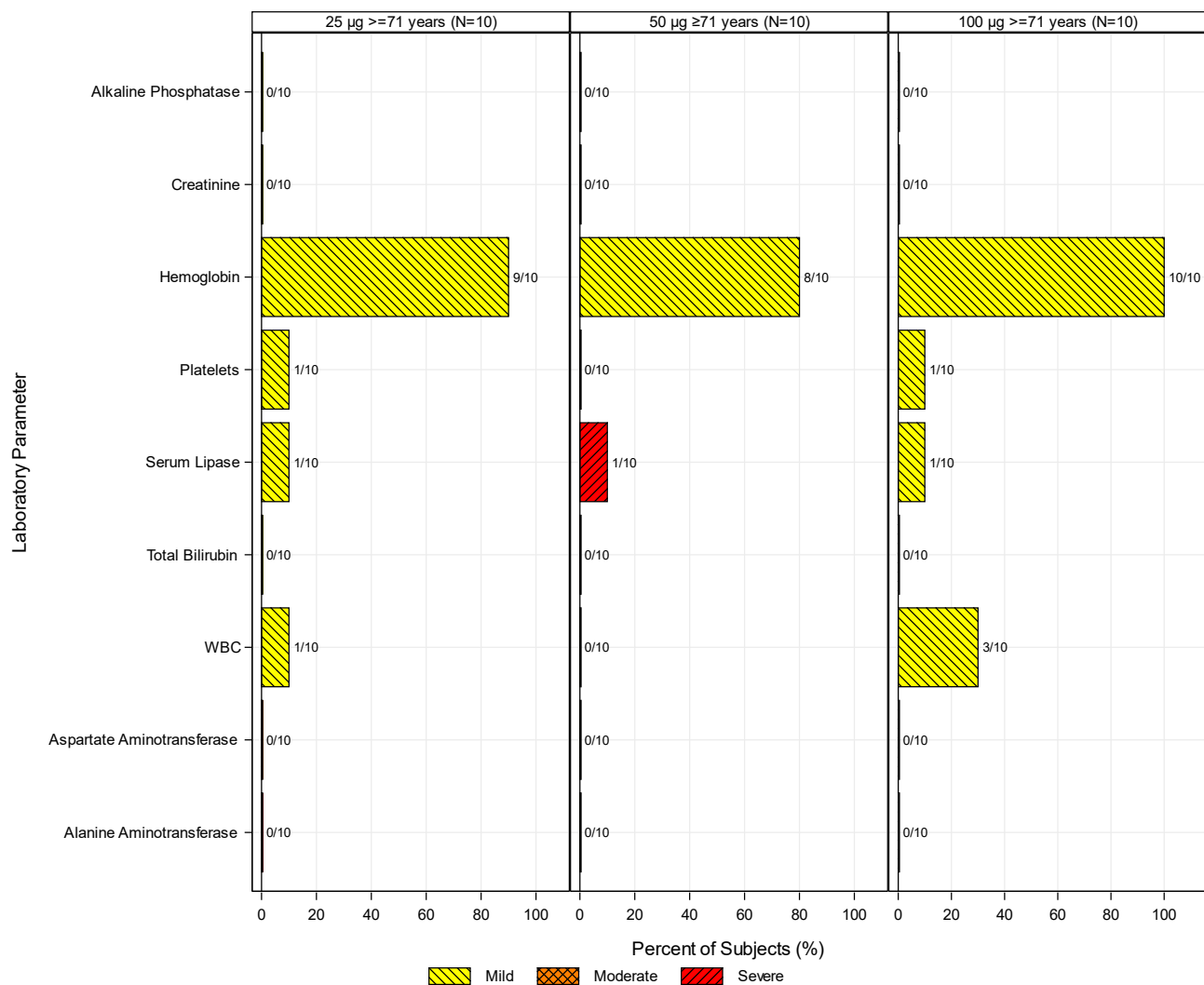


**FIGURE 5B:**  
**Clinical Laboratory Results by Severity and Vaccination Group 56-70 Years of Age**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**FIGURE 5C:**  
**Clinical Laboratory Results by Severity and Vaccination Group  $\geq 71$  Years of Age**



Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**TABLE 8A:**  
**Distribution of Protocol Deviations by Category, Type, and Vaccination Group 18-55 Years of Age**

|                                   |   | 25 µg<br>mRNA-1273<br>(N=15) |             | 50 µg<br>mRNA -1273<br>(N=15) |             | 100 µg<br>mRNA -1273<br>(N=15) |             | 250 µg<br>mRNA -1273<br>(N=15) |             | All Subjects<br>(N=60) |             |
|-----------------------------------|---|------------------------------|-------------|-------------------------------|-------------|--------------------------------|-------------|--------------------------------|-------------|------------------------|-------------|
| Category                          | Deviation Type                                | #of<br>Subj.                 | #of<br>Dev. | #of<br>Subj.                  | #of<br>Dev. | #of<br>Subj.                   | #of<br>Dev. | #of<br>Subj.                   | #of<br>Dev. | #of<br>Subj.           | #of<br>Dev. |
| Follow-up visit schedule          | Missed visit/visit not conducted              | -                            | -           | -                             | -           | -                              | -           | -                              | -           | -                      | -           |
|                                   | Out of window visit                           | -                            | -           | 2                             | 2           | 1                              | 2           | -                              | -           | 3                      | 4           |
| Protocol procedure/assessment     | Other: breach of confidentiality              | -                            | -           | -                             | -           | 1                              | 1           | -                              | -           | 1                      | 1           |
|                                   | Other: non-required lab tests performed       | 1                            | 1           | -                             | -           | -                              | -           | -                              | -           | 1                      | 1           |
|                                   | Other: v4 safety labs collected out of window | 1                            | 1           | -                             | -           | -                              | -           | -                              | -           | 1                      | 1           |
|                                   | Required procedure done incorrectly           | 1                            | 1           | 2                             | 2           | 2                              | 3           | 2                              | 2           | 7                      | 8           |
|                                   | Required procedure not conducted              | 1                            | 1           | -                             | -           | -                              | -           | 1                              | 1           | 2                      | 2           |
|                                   | Specimen result not obtained                  | -                            | -           | -                             | -           | -                              | -           | -                              | -           | -                      | -           |
|                                   | Too few aliquots obtained                     | -                            | -           | -                             | -           | 6                              | 9           | 2                              | 5           | 8                      | 14          |
| Treatment administration schedule | Required procedure done incorrectly           | -                            | -           | -                             | -           | -                              | -           | 1                              | 1           | 1                      | 1           |

**TABLE 8B:**  
**Distribution of Protocol Deviations by Category, Type, and Vaccination Group 56-70 Years of Age**

|                                   |   | 25 µg<br>mRNA-1273<br>(N=10) |          | 50 µg<br>mRNA -1273<br>(N=10) |          | 100 µg<br>mRNA-1273<br>(N=10) |          | All Subjects<br>(N=30) |          |
|-----------------------------------|---|------------------------------|----------|-------------------------------|----------|-------------------------------|----------|------------------------|----------|
| Category                          | Deviation Type                                | #of Subj.                    | #of Dev. | #of Subj.                     | #of Dev. | #of Subj.                     | #of Dev. | #of Subj.              | #of Dev. |
| Follow-up visit schedule          | Missed visit/visit not conducted              | -                            | -        | -                             | -        | 1                             | 1        | 1                      | 1        |
|                                   | Out of window visit                           | 1                            | 1        | -                             | -        | -                             | -        | 1                      | 1        |
| Protocol procedure/assessment     | Other: breach of confidentiality              | -                            | -        | -                             | -        | -                             | -        | -                      | -        |
|                                   | Other: non-required lab tests performed       | -                            | -        | -                             | -        | -                             | -        | -                      | -        |
|                                   | Other: v4 safety labs collected out of window | -                            | -        | -                             | -        | -                             | -        | -                      | -        |
|                                   | Required procedure done incorrectly           | -                            | -        | -                             | -        | -                             | -        | -                      | -        |
|                                   | Required procedure not conducted              | -                            | -        | -                             | -        | -                             | -        | -                      | -        |
|                                   | Specimen result not obtained                  | -                            | -        | -                             | -        | -                             | -        | -                      | -        |
|                                   | Too few aliquots obtained                     | 2                            | 2        | -                             | -        | -                             | -        | 2                      | 2        |
| Treatment administration schedule | Required procedure done incorrectly           | -                            | -        | -                             | -        | -                             | -        | -                      | -        |

**TABLE 8C:**  
**Distribution of Protocol Deviations by Category, Type, and Vaccination Group  $\geq 71$  Years of Age**

|                                   |   | 25 µg<br>mRNA-1273<br>(N=10) |          | 50 µg<br>mRNA -1273<br>(N=10) |          | 100 µg<br>mRNA-1273<br>(N=10) |          | All Subjects<br>(N=30) |          |
|-----------------------------------|---|------------------------------|----------|-------------------------------|----------|-------------------------------|----------|------------------------|----------|
| Category                          | Deviation Type                                | #of Subj.                    | #of Dev. | #of Subj.                     | #of Dev. | #of Subj.                     | #of Dev. | #of Subj.              | #of Dev. |
| Follow-up visit schedule          | Missed visit/visit not conducted              | -                            | -        | -                             | -        | -                             | -        | -                      | -        |
|                                   | Out of window visit                           | -                            | -        | -                             | -        | -                             | -        | -                      | -        |
| Protocol procedure/assessment     | Other: breach of confidentiality              | -                            | -        | -                             | -        | -                             | -        | -                      | -        |
|                                   | Other: non-required lab tests performed       | -                            | -        | -                             | -        | -                             | -        | -                      | -        |
|                                   | Other: v4 safety labs collected out of window | -                            | -        | -                             | -        | -                             | -        | -                      | -        |
|                                   | Required procedure done incorrectly           | -                            | -        | -                             | -        | -                             | -        | -                      | -        |
|                                   | Required procedure not conducted              | -                            | -        | -                             | -        | -                             | -        | -                      | -        |
|                                   | Specimen result not obtained                  | -                            | -        | -                             | -        | 1                             | 1        | 1                      | 1        |
|                                   | Too few aliquots obtained                     | 1                            | 1        | -                             | -        | 2                             | 2        | 3                      | 3        |
| Treatment administration schedule | Required procedure done incorrectly           | -                            | -        | -                             | -        | -                             | -        | -                      | -        |

**CLINICAL RESEARCH IN INFECTIOUS DISEASES**

**SAFETY SUMMARY REPORT**

**Prepared for DMID Protocol 20-0003:**

**Phase I, Open-Label, Dose-Ranging Study of the Safety and  
Immunogenicity of 2019-nCoV Vaccine (mRNA-1273) in Healthy  
Adults**

**APPENDICES**

**26 OCTOBER 2020**

Prepared and distributed by:  
Statistical and Data Coordinating Center (SDCC)  
Emmes  
Rockville, Maryland

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## TABLE OF CONTENTS

|   |     |
|---|-----|
| APPENDIX A: Adverse Event Definitions .....   | 2   |
| APPENDIX B: Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events ..... | 5   |
| APPENDIX C1: Solicited Systemic Events.....   | 60  |
| APPENDIX C2: Solicited Local Events .....   | 230 |
| APPENDIX D: Attribution for Systemic Solicited Events that Contribute to Halting Criteria .....   | 383 |
| APPENDIX E: Listing of Abnormal Clinical Laboratory Results.....                                  | 384 |
| APPENDIX F: Vital Signs Listing .....   | 848 |
| APPENDIX G1: Listing of Protocol Deviations.....  | 926 |
| APPENDIX G2: Listing of Non-Subject Deviations .....  | 934 |
| APPENDIX H: Listing of Pregnancies .....  | 935 |

## APPENDIX A: Adverse Event Definitions

*(Excerpted from Protocol version 4.0, 20 May 2020)*

### **Definition of Adverse Event (AE)**

AEs means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)). An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of medicinal (investigational) product.

Any medical condition that is present at the time that the subject is screened will be considered as baseline and not reported as an AE. However, if the severity of any pre-existing medical condition increases, it should be recorded as an AE.

AEs can be further divided into solicited AEs and unsolicited AEs. Solicited AEs are those for which the study team will specifically query the subject whether they occurred. Unsolicited AEs are those events that the subject report occurring without being queried about the specific event.

All AEs will be assessed for severity and relationship to study intervention (see section 8.3.3 of the protocol). Reporting of all AEs, solicited and unsolicited, will occur during the period from study product administration at Day 1 through 28 days after the last vaccination. After Day 57 through the end of study on Day 394, only SAEs, MAAEs, and NOCMCs will be recorded as AEs.

All AEs, solicited and unsolicited, will be captured on the appropriate DCF. Information to be collected for AEs includes event description, date of onset, assessment of severity, relationship to study product and alternate etiology (assessed only by those with the training and authority to make a diagnosis and listed on the Form FDA 1572 as the participating site PI or appropriate sub-investigator), date of resolution, seriousness, and outcome. AEs occurring during the study-collection and reporting period will be documented appropriately regardless of relationship.

AEs will be followed to resolution or stabilization.

**Severity of Adverse Events:** All AEs or SAEs will be assessed for severity, according to the toxicity grading scales in the FDA “Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials”.

For AEs not included in the protocol-defined grading system, the following guidelines will be used to describe severity.

- **Mild (Grade 1):** Events that are usually transient and may require only minimal or no treatment or therapeutic intervention and generally do not interfere with the subject’s usual activities of daily living.
- **Moderate (Grade 2):** Events that are usually alleviated with additional specific therapeutic intervention. The event interferes with usual activities of daily living, causing discomfort but poses no significant or permanent risk of harm to the research subject.

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



## **Appendix A (continued)** **Adverse Events Definitions**

*(Excerpted from Protocol version 4.0, 20 May 2020)*

- **Severe (Grade 3):** Events interrupt usual activities of daily living, or significantly affects clinical status, or may require intensive therapeutic intervention. Severe events are usually incapacitating.

AEs characterized as intermittent require documentation of onset and duration of each episode. The start and stop date of each reported AE will be recorded on the appropriate DCF. Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of intensity.

**Relationship to Study Intervention:** For each reported adverse reaction, the participating site PI or qualified designee must assess the relationship of the event to the study product using the following guidelines:

- **Related** – The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study intervention and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE.
- **Not Related** – There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.

### **Definition of Serious Adverse Event (SAE)**

An SAE is defined in 21 CFR 312.32 as follows: “An AE or suspected adverse reaction is considered serious if, in the view of either the participating site PI or appropriate sub-investigator or the sponsor, it results in any of the following outcomes:

- Death,
- a life-threatening AE,
- inpatient hospitalization or prolongation of existing hospitalization,
- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions,
- or a congenital anomaly/birth defect.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix A (continued)**  
**Adverse Events Definitions**

*(Excerpted from Protocol version 4.0, 20 May 2020)*

“Life-threatening” refers to an AE that at occurrence represents an immediate risk of death to a subject. An event that may cause death if it occurs in a more severe form is not considered life-threatening. Similarly, a hospital admission for an elective procedure is not considered an SAE.

All SAEs, as with any AE, will be assessed for severity and relationship to study intervention.

All SAEs will be recorded on the appropriate SAE DCF.

All SAEs will be followed through resolution or stabilization by a study clinician, licensed to make medical diagnoses and listed on the Form FDA 1572 as the participating site PI or appropriate sub-investigator.

All SAEs will be reviewed and evaluated by DMID and will be sent to the SMC (for periodic review unless related) and IRB/IEC.

**APPENDIX B:**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                 | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                      | MedDRA® Preferred Term |
|--|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|---|------------------------|
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 01, Subject ID: CV01KP005, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |   |                        |
| Petechiae R Elbow  | 14 (8)   | Mild     | Related                     | N/A  | Dose not changed                    | No                             | Recovered /resolved | Skin and subcutaneous tissue disorders          | Petechiae              |
| Comments:  |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 01, Subject ID: CV01KP007, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |   |                        |
| Vomiting   | 0 (0)  | Mild     | Not related                 | Other: brushing tongue                               | Dose not changed                    | No                             | Recovered /resolved | Gastrointestinal disorders                      | Vomiting               |
| Comments:  |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 01, Subject ID: CV01KP007, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |   |                        |
| Shortness of Breath With Strenuous Activity  | 25 (17)  | Mild     | Not related                 | Other: Deconditioning                                | Dose not changed                    | No                             | Recovered /resolved | Respiratory, thoracic and mediastinal disorders | Dyspnoea exertional    |
| Comments:  |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 01, Subject ID: CV01KP011, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |   |                        |
| Abdominal Gas  | 4 (0)  | Mild     | Not related                 | Other medical condition or illness: food intolerance | Dose not changed                    | No                             | Recovered /resolved | Gastrointestinal disorders                      | Flatulence             |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology       | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                      | MedDRA® Preferred Term |
|--|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|---|------------------------|
| Comments:  |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 01, Subject ID: CV01KP011, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |   |                        |
| Systolic Hypertension  | 28 (8)   | Mild     | Not related                 | Other: Recent exertion                     | Dose not changed                    | No                             | Recovered /resolved | Vascular disorders                              | Systolic hypertension  |
| Comments:  |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 01, Subject ID: CV01KP015, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |   |                        |
| Erythema   | 14 (14)  | Mild     | Not related                 | Study procedure: reaction to tape adhesive | Dose not changed                    | No                             | Recovered /resolved | Skin and subcutaneous tissue disorders          | Erythema               |
| Comments:  |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 01, Subject ID: CV01KP018, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |   |                        |
| Sore Throat  | 1 (3)  | Mild     | Related                     | N/A  | Dose not changed                    | No                             | Recovered /resolved | Respiratory, thoracic and mediastinal disorders | Oropharyngeal pain     |
| Comments:  |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 01, Subject ID: CV01KP018, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |   |                        |
| Sore Throat  | 15 (2)   | Mild     | Not related                 | Other: environmental                       | Dose not changed                    | No                             | Recovered /resolved | Respiratory, thoracic and mediastinal disorders | Oropharyngeal pain     |
| Comments:  |  |          |                             |  |                                     |                                |                     |   |                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology               | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                           | MedDRA® Preferred Term      |
|--|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|--|-----------------------------|
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 01, Subject ID: CV01KP023, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |  |                             |
| Bruise at Blood Draw Site  | 8 (6)  | Mild     | Not related                 | Study procedure: venipuncture trauma               | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Vessel puncture site bruise |
| Comments:  |  |          |                             |  |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 01, Subject ID: CV01KP024, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |  |                             |
| Right Neck Strain  | 6 (2)  | Mild     | Not related                 | Other medical condition or illness: lifting weight | Dose not changed                    | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Muscle strain               |
| Comments:  |  |          |                             |  |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 01, Subject ID: CV01KP026, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |  |                             |
| Contact Dermatitis   | 3 (9)  | Mild     | Not related                 | Study procedure: tape adhesive reaction            | Dose not changed                    | No                             | Recovered /resolved | Skin and subcutaneous tissue disorders               | Dermatitis contact          |
| Comments:  |  |          |                             |  |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 01, Subject ID: CV01KP026, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |  |                             |
| Cut On Right Index Finger  | 2 (2)  | Mild     | Not related                 | Other: accidental trauma                           | Dose not changed                    | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Skin laceration             |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                           | MedDRA® Preferred Term      |
|---|--|----------|-----------------------------|--------------------------------------|-------------------------------------|--------------------------------|---------------------|--|-----------------------------|
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 01, Subject ID: CV01KP028, AE Number: 001</b>  |  |          |                             |                                      |                                     |                                |                     |  |                             |
| Vomiting  | 1 (0)  | Moderate | Related                     | N/A                                  | Dose not changed                    | No                             | Recovered /resolved | Gastrointestinal disorders                           | Vomiting                    |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 01, Subject ID: CV01KP028, AE Number: 002</b>  |  |          |                             |                                      |                                     |                                |                     |  |                             |
| Hives On Lower Extremities  | 5 (1)  | Mild     | Related                     | N/A                                  | WD- Drug withdrawn                  | No                             | Recovered /resolved | Skin and subcutaneous tissue disorders               | Urticaria                   |
| Comments: Has had episodes about once per year of hives in past, sometimes due to cat allergy and other times without known etiology. Denies noting relationship to particular activity but occurs when outdoors. |  |          |                             |                                      |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 01, Subject ID: CV01KP031, AE Number: 001</b>  |  |          |                             |                                      |                                     |                                |                     |  |                             |
| Arm Weakness  | 0 (0)  | Mild     | Related                     | N/A                                  | Dose not changed                    | No                             | Recovered /resolved | Musculoskeletal and connective tissue disorders      | Muscular weakness           |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 01, Subject ID: CV01KP031, AE Number: 002</b>  |  |          |                             |                                      |                                     |                                |                     |  |                             |
| Bruise at Blood Draw Site   | 0 (8)  | Mild     | Not related                 | Study procedure: venipuncture trauma | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Vessel puncture site bruise |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 01, Subject ID: CV01KP031, AE Number: 003</b>  |  |          |                             |                                      |                                     |                                |                     |  |                             |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology   | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® Sytem Organ Class                            | MedDRA® Preferred Term      |
|--|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|--|-----------------------------|
| Bruise at Blood Draw Site  | 8 (3)  | Mild     | Not related                 | Study procedure: venipuncture trauma   | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Vessel puncture site bruise |
| Comments:  |  |          |                             |  |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 02, Subject ID: CV01KP005, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |  |                             |
| Left Palm Abrasion   | 5 (7)  | Mild     | Not related                 | Other: Trauma  | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Skin abrasion               |
| Comments:  |  |          |                             |  |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 02, Subject ID: CV01KP005, AE Number: 003</b> |  |          |                             |  |                                     |                                |                     |  |                             |
| Jaw Pain   | 36 (61)  | Mild     | Not related                 | Other: eating large sandwiches   | Not applicable                      | No                             | Recovered /resolved | Musculoskeletal and connective tissue disorders      | Pain in jaw                 |
| Comments:  |  |          |                             |  |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 02, Subject ID: CV01KP005, AE Number: 004</b> |  |          |                             |  |                                     |                                |                     |  |                             |
| Hordeolum Exacerbation   | 55 (Ongoing)                                       | Moderate | Not related                 | Other medical condition or illness: hordeolum present prior to study; worsened | Not applicable                      | No                             |                     | Infections and infestations                          | Hordeolum                   |
| Comments:  |  |          |                             |  |                                     |                                |                     |  |                             |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                    | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® Sytem Organ Class                            | MedDRA® Preferred Term |
|--|--|----------|-----------------------------|---|-------------------------------------|--------------------------------|---------------------|--|------------------------|
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 02, Subject ID: CV01KP006, AE Number: 001</b>                                 |  |          |                             |   |                                     |                                |                     |  |                        |
| Infected Pustules  | 47 (42)  | Mild     | Not related                 | Other medical condition or illness: Bacterial infection | Not applicable                      | No                             | Recovered /resolved | Infections and infestations                          | Pustule                |
| Comments: Telehealth visit 5June2020 for localized erythema and swelling of possible insect bite to L inner thigh.               |  |          |                             |   |                                     |                                |                     |  |                        |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 02, Subject ID: CV01KP010, AE Number: 001</b>                                 |  |          |                             |   |                                     |                                |                     |  |                        |
| Vomiting   | 22 (1)   | Moderate | Not related                 | Other medical condition or illness: Sinus Headache      | Not applicable                      | No                             | Recovered /resolved | Gastrointestinal disorders                           | Vomiting               |
| Comments:  |  |          |                             |   |                                     |                                |                     |  |                        |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 02, Subject ID: CV01KP010, AE Number: 002</b>                                 |  |          |                             |   |                                     |                                |                     |  |                        |
| Fatigue  | 20 (3)   | Mild     | Not related                 | Other medical condition or illness: Seasonal Allergies  | Not applicable                      | No                             | Recovered /resolved | General disorders and administration site conditions | Fatigue                |
| Comments: Had mild fatigue (in retrospect) for 2 days prior to onset of sinus headache. Seasonal allergies are asymptomatic now. |  |          |                             |   |                                     |                                |                     |  |                        |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 02, Subject ID: CV01KP011, AE Number: 003</b>                                 |  |          |                             |   |                                     |                                |                     |  |                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology           | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA <sup>®</sup> Sytem Organ Class                | MedDRA <sup>®</sup> Preferred Term |
|--|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|--|------------------------------------|
| Contusions   | 74 (12)  | Mild     | Not related                 | Other: altercation                             | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Contusion                          |
| Comments: involved in altercation where he was thrown to ground, striking L head and L shoulder  |  |          |                             |  |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 02, Subject ID: CV01KP026, AE Number: 003</b>   |  |          |                             |  |                                     |                                |                     |  |                                    |
| Skin Irritation Encircling Injection Site  | 1 (8)  | Mild     | Not related                 | Study procedure: skin irritation from band aid | Not applicable                      | No                             | Recovered /resolved | General disorders and administration site conditions | Injection site irritation          |
| Comments: Reddened, puffy skin the size and shape of the dot bandaid place over the injection site. No reaction in the center of the circle. |  |          |                             |  |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 02, Subject ID: CV01KP026, AE Number: 004</b>   |  |          |                             |  |                                     |                                |                     |  |                                    |
| Bruises  | 14 (17)  | Mild     | Not related                 | Other: trauma from heavy weight                | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Contusion                          |
| Comments: on forearms after moving furniture   |  |          |                             |  |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 02, Subject ID: CV01KP026, AE Number: 005</b>   |  |          |                             |  |                                     |                                |                     |  |                                    |
| Presyncope   | 18 (0)   | Mild     | Not related                 | Other: Sudden postural change                  | Not applicable                      | No                             | Recovered /resolved | Nervous system disorders                             | Presyncope                         |
| Comments:  |  |          |                             |  |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 02, Subject ID: CV01KP031, AE Number: 004</b>   |  |          |                             |  |                                     |                                |                     |  |                                    |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA <sup>®</sup> Sytem Organ Class                | MedDRA <sup>®</sup> Preferred Term |
|--|--|----------|-----------------------------|--------------------------------------|-------------------------------------|--------------------------------|---------------------|--|------------------------------------|
| Bruise at Blood Draw Site  | 8 (7)  | Mild     | Not related                 | Study procedure: Venipuncture trauma | Not applicable                      | No                             | Recovered /resolved | General disorders and administration site conditions | Vessel puncture site bruise        |
| Comments:  |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 02, Subject ID: CV01KP031, AE Number: 005</b> |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| Muscle Strain  | 11 (3)   | Mild     | Not related                 | Other: heavy lifting                 | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Muscle strain                      |
| Comments:  |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 02, Subject ID: CV01KP031, AE Number: 006</b> |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| Bruise   | 25 (4)   | Mild     | Not related                 | Other: trauma from carrying load     | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Contusion                          |
| Comments: 4 cm bruise on R shoulder  |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 25 µg (18-55 years), Dose #: 02, Subject ID: CV01KP031, AE Number: 007</b> |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| Puncture Wound   | 72 (26)  | Mild     | Not related                 | Other: Foreign body                  | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Wound                              |
| Comments: Stepped on nail  |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 01, Subject ID: CV01EM051, AE Number: 001</b> |  |          |                             |                                      |                                     |                                |                     |  |                                    |

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                   | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® Sytem Organ Class                            | MedDRA® Preferred Term      |
|--|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|--|-----------------------------|
| Stuffy Nose  | 3 (3)  | Mild     | Related                     | N/A  | Dose not changed                    | No                             | Recovered /resolved | Respiratory, thoracic and mediastinal disorders      | Nasal congestion            |
| Comments:  |  |          |                             |  |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 01, Subject ID: CV01EM051, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |  |                             |
| Bruising at Blood Draw Site  | 0 (10)   | Mild     | Not related                 | Study procedure: Phlebotomy                            | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Vessel puncture site bruise |
| Comments:  |  |          |                             |  |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 01, Subject ID: CV01EM051, AE Number: 003</b> |  |          |                             |  |                                     |                                |                     |  |                             |
| Nasal Congestion   | 16 (2)   | Moderate | Not related                 | Other medical condition or illness: seasonal allergies | Dose not changed                    | No                             | Recovered /resolved | Respiratory, thoracic and mediastinal disorders      | Nasal congestion            |
| Comments:  |  |          |                             |  |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 01, Subject ID: CV01EM051, AE Number: 004</b> |  |          |                             |  |                                     |                                |                     |  |                             |
| Skin Abrasion  | 16 (6)   | Mild     | Not related                 | Other: Trauma  | Dose not changed                    | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Skin abrasion               |
| Comments:  |  |          |                             |  |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 01, Subject ID: CV01EM053, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |  |                             |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                      | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome               | MedDRA® System Organ Class             | MedDRA® Preferred Term |
|---|--|----------|-----------------------------|---|-------------------------------------|--------------------------------|-----------------------|--|------------------------|
| Abdominal Pain  | 17 (3)   | Moderate | Not related                 | Other medical condition or illness: Ruptured Ovarian Cyst | Dose not changed                    | No                             | Recovered /resolved   | Gastrointestinal disorders             | Abdominal pain         |
| Comments: Had seen MD on 22Jun2020, an ultrasound was obtained that documented a ruptured ovarian cyst. |  |          |                             |   |                                     |                                |                       |  |                        |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 01, Subject ID: CV01EM054, AE Number: 001</b>        |  |          |                             |   |                                     |                                |                       |  |                        |
| Rash  | 21 (13)  | Mild     | Not related                 | Other medical condition or illness: Poison Ivy            | Dose not changed                    | No                             | Recovered /resolved   | Skin and subcutaneous tissue disorders | Rash                   |
| Comments:   |  |          |                             |   |                                     |                                |                       |  |                        |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 01, Subject ID: CV01EM054, AE Number: 002</b>        |  |          |                             |   |                                     |                                |                       |  |                        |
| Seasonal Allergies  | 17 (Ongoing)                                       | Mild     | Not related                 | Other: Environmental Exposure                             | Dose not changed                    | No                             | Recovering /resolving | Immune system disorders                | Seasonal allergy       |
| Comments: Itchy eyes, itchy throat  |  |          |                             |   |                                     |                                |                       |  |                        |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 01, Subject ID: CV01HC051, AE Number: 001</b>        |  |          |                             |   |                                     |                                |                       |  |                        |
| Lymphadenopathy   | 0 (3)  | Mild     | Related                     | N/A   | Dose not changed                    | No                             | Recovered /resolved   | Blood and lymphatic system disorders   | Lymphadenopathy        |
| Comments: AE started after treatment administration on 05JUN2020.                                       |  |          |                             |   |                                     |                                |                       |  |                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology  | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                           | MedDRA® Preferred Term               |
|--|--|----------|-----------------------------|---------------------------------------|-------------------------------------|--------------------------------|---------------------|--|--------------------------------------|
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 01, Subject ID: CV01KP095, AE Number: 001</b> |  |          |                             |                                       |                                     |                                |                     |  |                                      |
| Vaccinated Arm Weakness  | 0 (0)  | Mild     | Related                     | N/A                                   | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Vaccination site movement impairment |
| Comments:  |  |          |                             |                                       |                                     |                                |                     |  |                                      |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 01, Subject ID: CV01KP096, AE Number: 001</b> |  |          |                             |                                       |                                     |                                |                     |  |                                      |
| Low Blood Sugar  | 13 (0)   | Mild     | Not related                 | Other: inadequate intake for activity | Dose not changed                    | No                             | Recovered /resolved | Investigations                                       | Blood glucose decreased              |
| Comments: nausea, lightheadedness  |  |          |                             |                                       |                                     |                                |                     |  |                                      |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 01, Subject ID: CV01KP097, AE Number: 001</b> |  |          |                             |                                       |                                     |                                |                     |  |                                      |
| Abrasions  | 24 (6)   | Mild     | Not related                 | Other: Bicycle fall                   | Dose not changed                    | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Skin abrasion                        |
| Comments:  |  |          |                             |                                       |                                     |                                |                     |  |                                      |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 01, Subject ID: CV01KP097, AE Number: 002</b> |  |          |                             |                                       |                                     |                                |                     |  |                                      |
| Uri  | 20 (3)   | Mild     | Not related                 | Other: Viral illness                  | Dose not changed                    | No                             | Recovered /resolved | Infections and infestations                          | Upper respiratory tract infection    |
| Comments:  |  |          |                             |                                       |                                     |                                |                     |  |                                      |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 01, Subject ID: CV01KP098, AE Number: 001</b> |  |          |                             |                                       |                                     |                                |                     |  |                                      |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                   | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                      | MedDRA® Preferred Term      |
|--|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|---|-----------------------------|
| Indigestion  | 4 (0)  | Mild     | Not related                 | Other: Food  | Dose not changed                    | No                             | Recovered /resolved | Gastrointestinal disorders                      | Dyspepsia                   |
| Comments:  |  |          |                             |  |                                     |                                |                     |   |                             |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 01, Subject ID: CV01KP098, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |   |                             |
| Muscle Soreness  | 14 (1)   | Mild     | Not related                 | Other: overuse   | Dose not changed                    | No                             | Recovered /resolved | Musculoskeletal and connective tissue disorders | Myalgia                     |
| Comments:  |  |          |                             |  |                                     |                                |                     |   |                             |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 02, Subject ID: CV01EM051, AE Number: 005</b> |  |          |                             |  |                                     |                                |                     |   |                             |
| Post Nasal Drip  | 1 (5)  | Mild     | Related                     | N/A  | Not applicable                      | No                             | Recovered /resolved | Respiratory, thoracic and mediastinal disorders | Upper-airway cough syndrome |
| Comments:  |  |          |                             |  |                                     |                                |                     |   |                             |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 02, Subject ID: CV01EM051, AE Number: 006</b> |  |          |                             |  |                                     |                                |                     |   |                             |
| Post Nasal Drip  | 14 (13)  | Mild     | Not related                 | Other medical condition or illness: Seasonal Allergies | Not applicable                      | No                             | Recovered /resolved | Respiratory, thoracic and mediastinal disorders | Upper-airway cough syndrome |
| Comments:  |  |          |                             |  |                                     |                                |                     |   |                             |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 02, Subject ID: CV01EM053, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |   |                             |
| Diarrhea   | 1 (1)  | Moderate | Related                     | N/A  | Not applicable                      | No                             | Recovered /resolved | Gastrointestinal disorders                      | Diarrhoea                   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                   | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                      | MedDRA® Preferred Term |
|---|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|---|------------------------|
| Comments:   |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 02, Subject ID: CV01EM053, AE Number: 003</b>  |  |          |                             |  |                                     |                                |                     |   |                        |
| Sore Throat   | 20 (3)   | Mild     | Not related                 | Other medical condition or illness: Seasonal allergies | Not applicable                      | No                             | Recovered /resolved | Respiratory, thoracic and mediastinal disorders | Oropharyngeal pain     |
| Comments:   |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 02, Subject ID: CV01KP094, AE Number: 001</b>  |  |          |                             |  |                                     |                                |                     |   |                        |
| Back Spasm  | 1 (0)  | Mild     | Related                     | N/A  | Not applicable                      | No                             | Recovered /resolved | Musculoskeletal and connective tissue disorders | Muscle spasms          |
| Comments: 7/15/2020 Subject woke at 2am on 7/14/20 after receiving second vaccine on 7/13/20. Her back has a spasm and then she continued to have body aches throughout the night. Took aspirin in the morning, did not work in the morning. Symptoms had resolved by midday and subject resumed normal activities. |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 02, Subject ID: CV01KP094, AE Number: 002</b>  |  |          |                             |  |                                     |                                |                     |   |                        |
| Vertigo   | 77 (0)   | Mild     | Not related                 | Other medical condition or illness: Cerumen impaction  | Not applicable                      | No                             | Recovered /resolved | Ear and labyrinth disorders                     | Vertigo                |
| Comments:   |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 02, Subject ID: CV01KP096, AE Number: 002</b>  |  |          |                             |  |                                     |                                |                     |   |                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                           | MedDRA® Preferred Term           |
|--|--|----------|-----------------------------|---|-------------------------------------|--------------------------------|---------------------|--|----------------------------------|
| Exacerbation of Impacted Wisdom Teeth  | 2 (5)  | Moderate | Not related                 | Other medical condition or illness: dental crowding | Not applicable                      | No                             | Recovered /resolved | Gastrointestinal disorders                           | Tooth impacted                   |
| Comments:  |  |          |                             |   |                                     |                                |                     |  |                                  |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 02, Subject ID: CV01KP096, AE Number: 003</b> |  |          |                             |   |                                     |                                |                     |  |                                  |
| Bradycardia  | 9 (0)  | Mild     | Not related                 | Other: Physical conditionin g                       | Not applicable                      | No                             | Recovered /resolved | Cardiac disorders                                    | Bradycardia                      |
| Comments:  |  |          |                             |   |                                     |                                |                     |  |                                  |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 02, Subject ID: CV01KP098, AE Number: 003</b> |  |          |                             |   |                                     |                                |                     |  |                                  |
| Bradycardia  | 7 (7)  | Mild     | Related                     | N/A   | Not applicable                      | No                             | Recovered /resolved | Cardiac disorders                                    | Bradycardia                      |
| Comments:  |  |          |                             |   |                                     |                                |                     |  |                                  |
| <b>Vaccination Group: 50 µg (18-55 years), Dose #: 02, Subject ID: CV01KP101, AE Number: 001</b> |  |          |                             |   |                                     |                                |                     |  |                                  |
| Ecchymosis at Blood Draw Site  | 7 (19)   | Mild     | Not related                 | Study procedure: phlebotomy needle trauma           | Not applicable                      | No                             | Recovered /resolved | General disorders and administration site conditions | Vessel puncture site haemorrhage |
| Comments:  |  |          |                             |   |                                     |                                |                     |  |                                  |
| <b>Vaccination Group: 50 µg (56-70 years), Dose #: 01, Subject ID: CV01VR005, AE Number: 001</b> |  |          |                             |   |                                     |                                |                     |  |                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                     | MedDRA® Preferred Term |
|---|--|----------|-----------------------------|--------------------------------------|-------------------------------------|--------------------------------|---------------------|--|------------------------|
| Bradycardia   | 26 (0)   | Mild     | Not related                 | Other: distance runner               | Dose not changed                    | No                             | Recovered /resolved | Cardiac disorders                              | Bradycardia            |
| Comments: Heart rate was 52 prior to vaccination and 56 about 1 hour after administration of the 2nd study vaccine.   |  |          |                             |                                      |                                     |                                |                     |  |                        |
| <b>Vaccination Group: 50 µg (56-70 years), Dose #: 01, Subject ID: CV01VR009, AE Number: 001</b>  |  |          |                             |                                      |                                     |                                |                     |  |                        |
| Gastrointestinal Discomfort   | 4 (0)  | Moderate | Related                     | N/A                                  | Dose not changed                    | No                             | Recovered /resolved | Gastrointestinal disorders                     | Abdominal discomfort   |
| Comments: Complaint of nausea and lower abdominal cramping that resulted in interference with her usual activities. Symptoms resolved spontaneously within 3 hours. |  |          |                             |                                      |                                     |                                |                     |  |                        |
| <b>Vaccination Group: 50 µg (56-70 years), Dose #: 01, Subject ID: CV01VR017, AE Number: 001</b>  |  |          |                             |                                      |                                     |                                |                     |  |                        |
| Muscle Strain   | 17 (11)  | Mild     | Not related                 | Other: injury                        | Dose not changed                    | No                             | Recovered /resolved | Injury, poisoning and procedural complications | Muscle strain          |
| Comments: Strained left shoulder while opening her van  |  |          |                             |                                      |                                     |                                |                     |  |                        |
| <b>Vaccination Group: 50 µg (56-70 years), Dose #: 01, Subject ID: CV01VR024, AE Number: 001</b>  |  |          |                             |                                      |                                     |                                |                     |  |                        |
| Laceration  | 3 (9)  | Mild     | Not related                 | Other: Fall                          | Dose not changed                    | No                             | Recovered /resolved | Injury, poisoning and procedural complications | Skin laceration        |
| Comments: laceration on forehead resulting from a fall  |  |          |                             |                                      |                                     |                                |                     |  |                        |
| <b>Vaccination Group: 50 µg (56-70 years), Dose #: 02, Subject ID: CV01VR003, AE Number: 001</b>  |  |          |                             |                                      |                                     |                                |                     |  |                        |

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology   | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome               | MedDRA® System Organ Class                     | MedDRA® Preferred Term |
|--|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|-----------------------|--|------------------------|
| Viral Syndrome   | 40 (27)  | Severe   | Not related                 | Other medical condition or illness: Viral syndrome most likely from community exposure | Not applicable                      | No                             | Recovered /resolved   | Infections and infestations                    | Viral infection        |
| Comments:  |  |          |                             |  |                                     |                                |                       |  |                        |
| <b>Vaccination Group: 50 µg (56-70 years), Dose #: 02, Subject ID: CV01VR005, AE Number: 002</b> |  |          |                             |  |                                     |                                |                       |  |                        |
| Cracked tooth  | 80 (Ongoing)                                       | Moderate | Not related                 | Other medical condition or illness: age-related  | Not applicable                      | No                             | Recovering /resolving | Injury, poisoning and procedural complications | Tooth fracture         |
| Comments:  |  |          |                             |  |                                     |                                |                       |  |                        |
| <b>Vaccination Group: 50 µg (56-70 years), Dose #: 02, Subject ID: CV01VR006, AE Number: 001</b> |  |          |                             |  |                                     |                                |                       |  |                        |
| Bradycardia  | 0 (6)  | Mild     | Not related                 | Other: His pulse has a tendency to run low   | Dose not changed                    | No                             | Recovered /resolved   | Cardiac disorders                              | Bradycardia            |
| Comments: His pulse was 53 about 1 hour after vaccination.                                       |  |          |                             |  |                                     |                                |                       |  |                        |
| <b>Vaccination Group: 50 µg (56-70 years), Dose #: 02, Subject ID: CV01VR028, AE Number: 001</b> |  |          |                             |  |                                     |                                |                       |  |                        |

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                           | MedDRA® Preferred Term  |
|--|--|----------|-----------------------------|--------------------------------------|-------------------------------------|--------------------------------|---------------------|--|-------------------------|
| Urinary Tract Infection  | 31 (40)  | Moderate | Not related                 | Other: bacterial infection           | Not applicable                      | No                             | Recovered /resolved | Infections and infestations                          | Urinary tract infection |
| Comments:  |  |          |                             |                                      |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 50 µg (≥71 years), Dose #: 01, Subject ID: CV01VR002, AE Number: 001</b>   |  |          |                             |                                      |                                     |                                |                     |  |                         |
| Traumatic Injuries   | 19 (21)  | Mild     | Not related                 | Other: Fall                          | Dose not changed                    | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Injury                  |
| Comments: Xray exam normal on 24JUN2020  |  |          |                             |                                      |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 50 µg (≥71 years), Dose #: 01, Subject ID: CV01VR013, AE Number: 001</b>   |  |          |                             |                                      |                                     |                                |                     |  |                         |
| Traumatic Injuries   | 20 (27)  | Mild     | Not related                 | Other: fell while running            | Dose not changed                    | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Injury                  |
| Comments: sustained abrasions to the right knee, right elbow and hands; mild right hip and buttock pain; mild pain on the right lateral chest wall |  |          |                             |                                      |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 50 µg (≥71 years), Dose #: 01, Subject ID: CV01VR018, AE Number: 001</b>   |  |          |                             |                                      |                                     |                                |                     |  |                         |
| Bruise at Injection Site   | 2 (30)   | Mild     | Not related                 | Study procedure: needle trauma       | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Injection site bruising |
| Comments:  |  |          |                             |                                      |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 50 µg (≥71 years), Dose #: 01, Subject ID: CV01VR023, AE Number: 001</b>   |  |          |                             |                                      |                                     |                                |                     |  |                         |

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology         | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                      | MedDRA® Preferred Term |
|--|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|---|------------------------|
| Hypertension   | 0 (6)  | Mild     | Not related                 | Other: Distressed due to a family phone call | Dose not changed                    | No                             | Recovered /resolved | Vascular disorders                              | Hypertension           |
| Comments: blood pressure measured 60 minutes post administration                               |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 50 µg (≥71 years), Dose #: 02, Subject ID: CV01VR002, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |   |                        |
| Tick Bite  | 35 (22)  | Mild     | Not related                 | Other: Tick Bite                             | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications  | Arthropod bite         |
| Comments:  |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 50 µg (≥71 years), Dose #: 02, Subject ID: CV01VR004, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |   |                        |
| Sore Throat  | 28 (1)   | Mild     | Not related                 | Other: dry air                               | Not applicable                      | No                             | Recovered /resolved | Respiratory, thoracic and mediastinal disorders | Oropharyngeal pain     |
| Comments:  |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 50 µg (≥71 years), Dose #: 02, Subject ID: CV01VR021, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |   |                        |

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology  | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                      | MedDRA® Preferred Term |
|---|--|----------|-----------------------------|---|-------------------------------------|--------------------------------|---------------------|---|------------------------|
| Hypertension  | 0 (28)   | Mild     | Not related                 | Other medical condition or illness: Subject forgot to take blood pressure medications | Dose not changed                    | No                             | Recovered /resolved | Vascular disorders                              | Hypertension           |
| Comments: Elevated blood pressure prior to product administration.                                |  |          |                             |   |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 01, Subject ID: CV01EM004, AE Number: 001</b> |  |          |                             |   |                                     |                                |                     |   |                        |
| Elevated Heart Rate   | 13 (14)  | Mild     | Not related                 | Other: Caffeine ingestion   | Dose not changed                    | No                             | Recovered /resolved | Investigations                                  | Heart rate increased   |
| Comments:   |  |          |                             |   |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 01, Subject ID: CV01EM007, AE Number: 001</b> |  |          |                             |   |                                     |                                |                     |   |                        |
| Sore Throat   | 4 (3)  | Mild     | Not related                 | Other medical condition or illness: Seasonal Allergies                                | Dose not changed                    | No                             | Recovered /resolved | Respiratory, thoracic and mediastinal disorders | Oropharyngeal pain     |
| Comments:   |  |          |                             |   |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 01, Subject ID: CV01EM007, AE Number: 002</b> |  |          |                             |   |                                     |                                |                     |   |                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology        | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                           | MedDRA® Preferred Term  |
|---|--|----------|-----------------------------|---|-------------------------------------|--------------------------------|---------------------|--|-------------------------|
| Lower Back Muscle Strain  | 9 (6)  | Moderate | Not related                 | Other: Exercise                             | Dose not changed                    | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Muscle strain           |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 01, Subject ID: CV01EM009, AE Number: 001</b> |  |          |                             |   |                                     |                                |                     |  |                         |
| Bruise On Arm at Injection Site   | 6 (6)  | Mild     | Not related                 | Study procedure: Related to injection       | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Injection site bruising |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 01, Subject ID: CV01EM010, AE Number: 001</b> |  |          |                             |   |                                     |                                |                     |  |                         |
| Burn On Wrist   | 14 (27)  | Mild     | Not related                 | Other: oven burn                            | Dose not changed                    | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Thermal burn            |
| Comments: 20 mm burn on left wrist from cooking   |  |          |                             |   |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 01, Subject ID: CV01HC008, AE Number: 001</b> |  |          |                             |   |                                     |                                |                     |  |                         |
| Dizziness   | 1 (1)  | Mild     | Not related                 | Study procedure: phlebotomy and dehydration | Dose not changed                    | No                             | Recovered /resolved | Nervous system disorders                             | Dizziness               |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 01, Subject ID: CV01KP008, AE Number: 001</b> |  |          |                             |   |                                     |                                |                     |  |                         |

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                           | MedDRA® Preferred Term  |
|---|--|----------|-----------------------------|--------------------------------------|-------------------------------------|--------------------------------|---------------------|--|-------------------------|
| Bruise at Injection Site  | 1 (13)   | Mild     | Not related                 | Study procedure: trauma from needle  | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Injection site bruising |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 01, Subject ID: CV01KP009, AE Number: 001</b> |  |          |                             |                                      |                                     |                                |                     |  |                         |
| Vasodilation On Bilateral Hands   | 3 (0)  | Mild     | Related                     | N/A                                  | Dose not changed                    | No                             | Recovered /resolved | Vascular disorders                                   | Vasodilatation          |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 01, Subject ID: CV01KP009, AE Number: 002</b> |  |          |                             |                                      |                                     |                                |                     |  |                         |
| Injection Site Itching  | 2 (0)  | Mild     | Related                     | N/A                                  | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Injection site pruritus |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 01, Subject ID: CV01KP012, AE Number: 001</b> |  |          |                             |                                      |                                     |                                |                     |  |                         |
| Bruise at Injection Site  | 0 (15)   | Mild     | Not related                 | Study procedure: Vaccine injection   | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Injection site bruising |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 01, Subject ID: CV01KP012, AE Number: 002</b> |  |          |                             |                                      |                                     |                                |                     |  |                         |
| Decreased Appetite  | 0 (7)  | Mild     | Related                     | N/A                                  | Dose not changed                    | No                             | Recovered /resolved | Metabolism and nutrition disorders                   | Decreased appetite      |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                   | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                           | MedDRA® Preferred Term  |
|---|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|--|-------------------------|
| Comments:   |  |          |                             |  |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 01, Subject ID: CV01KP012, AE Number: 003</b> |  |          |                             |  |                                     |                                |                     |  |                         |
| Itching at Injection Site   | 7 (1)  | Mild     | Related                     | N/A  | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Injection site pruritus |
| Comments:   |  |          |                             |  |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 01, Subject ID: CV01KP014, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |  |                         |
| Nasal Congestion  | 1 (0)  | Mild     | Not related                 | Other medical condition or illness: seasonal allergies | Dose not changed                    | No                             | Recovered /resolved | Respiratory, thoracic and mediastinal disorders      | Nasal congestion        |
| Comments:   |  |          |                             |  |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 01, Subject ID: CV01KP014, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |  |                         |
| R Breast Pain   | 20 (4)   | Mild     | Not related                 | Other: Premenstrual                                    | Dose not changed                    | No                             | Recovered /resolved | Reproductive system and breast disorders             | Breast pain             |
| Comments:   |  |          |                             |  |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 02, Subject ID: CV01EM009, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |  |                         |
| Bradycardia   | 14 (12)  | Mild     | Not related                 | Other: Conditioned athlete                             | Not applicable                      | No                             | Recovered /resolved | Cardiac disorders                                    | Bradycardia             |
| Comments:   |  |          |                             |  |                                     |                                |                     |  |                         |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology   | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class  | MedDRA® Preferred Term                   |
|---|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|-----------------------------|--|
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 02, Subject ID: CV01EM010, AE Number: 002</b>   |  |          |                             |  |                                     |                                |                     |                             |  |
| Gastroenteritis   | 78 (1)   | Moderate | Not related                 | Other medical condition or illness: Alcohol ingestion and fatty food ingestion | Not applicable                      | No                             | Recovered /resolved | Infections and infestations | Gastroenteritis                          |
| Comments:   |  |          |                             |  |                                     |                                |                     |                             |  |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 02, Subject ID: CV01EM010, AE Number: 003</b>   |  |          |                             |  |                                     |                                |                     |                             |  |
| Worsening Adhd Symptoms   | 21 (61)  | Moderate | Not related                 | Other medical condition or illness: ADHD                                       | Not applicable                      | No                             | Recovered /resolved | Psychiatric disorders       | Attention deficit hyperactivity disorder |
| Comments: Problems with concentration, trouble learning and paying attention to her online classes. |  |          |                             |  |                                     |                                |                     |                             |  |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 02, Subject ID: CV01EM012, AE Number: 001</b>   |  |          |                             |  |                                     |                                |                     |                             |  |
| Infected Cyst   | 61 (9)   | Moderate | Not related                 | Other medical condition or illness: Bacterial Infection                        | Not applicable                      | No                             | Recovered /resolved | Infections and infestations | Infected cyst                            |
| Comments: Underwent incision and drainage with purulence. Administered antibiotics                  |  |          |                             |  |                                     |                                |                     |                             |  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                      | MedDRA® Preferred Term |
|---|--|----------|-----------------------------|--------------------------------------|-------------------------------------|--------------------------------|---------------------|---|------------------------|
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 02, Subject ID: CV01HC001, AE Number: 001</b> |  |          |                             |                                      |                                     |                                |                     |   |                        |
| Abdominal Cramping  | 0 (1)  | Moderate | Related                     | N/A                                  | Dose not changed                    | No                             | Recovered /resolved | Gastrointestinal disorders                      | Abdominal pain         |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 02, Subject ID: CV01KP008, AE Number: 002</b> |  |          |                             |                                      |                                     |                                |                     |   |                        |
| Neck Pain   | 2 (1)  | Mild     | Not related                 | Other: Positional stress             | Not applicable                      | No                             | Recovered /resolved | Musculoskeletal and connective tissue disorders | Neck pain              |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 02, Subject ID: CV01KP008, AE Number: 003</b> |  |          |                             |                                      |                                     |                                |                     |   |                        |
| Back Muscle Strain  | 22 (48)  | Mild     | Not related                 | Other: positional                    | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications  | Muscle strain          |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 02, Subject ID: CV01KP009, AE Number: 003</b> |  |          |                             |                                      |                                     |                                |                     |   |                        |
| Diaphragmatic Cramping  | 1 (0)  | Mild     | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | Respiratory, thoracic and mediastinal disorders | Diaphragmatic spasm    |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 02, Subject ID: CV01KP012, AE Number: 004</b> |  |          |                             |                                      |                                     |                                |                     |   |                        |
| Decreased Appetite  | 0 (3)  | Mild     | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | Metabolism and nutrition disorders              | Decreased appetite     |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA <sup>®</sup> Sytem Organ Class                | MedDRA <sup>®</sup> Preferred Term |
|---|--|----------|-----------------------------|--------------------------------------|-------------------------------------|--------------------------------|---------------------|--|------------------------------------|
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 02, Subject ID: CV01KP012, AE Number: 005</b> |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| Feeling of Restlessness   | 1 (0)  | Moderate | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | General disorders and administration site conditions | Feeling jittery                    |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 02, Subject ID: CV01KP012, AE Number: 006</b> |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| Eye Irritation  | 1 (0)  | Mild     | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | Eye disorders  | Eye irritation                     |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 02, Subject ID: CV01KP012, AE Number: 007</b> |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| Stomach Upset   | 4 (0)  | Mild     | Not related                 | Other: dietary intolerance           | Not applicable                      | No                             | Recovered /resolved | Gastrointestinal disorders                           | Abdominal discomfort               |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 02, Subject ID: CV01KP012, AE Number: 008</b> |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| Itching at Injection Site   | 3 (0)  | Mild     | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | General disorders and administration site conditions | Injection site pruritus            |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 100 µg (18-55 years), Dose #: 02, Subject ID: CV01KP012, AE Number: 009</b> |  |          |                             |                                      |                                     |                                |                     |  |                                    |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                                   | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® Sytem Organ Class          | MedDRA® Preferred Term |
|---|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|------------------------------------|------------------------|
| Dark Stools   | 4 (11)   | Mild     | Not related                 | Other: Dietary change  | Not applicable                      | No                             | Recovered /resolved | Gastrointestinal disorders         | Faeces discoloured     |
| Comments:   |  |          |                             |  |                                     |                                |                     |                                    |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01EM003, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |                                    |                        |
| Headache  | 10 (0)   | Moderate | Not related                 | Other medical condition or illness: has a baseline history of Headache | Dose not changed                    | No                             | Recovered /resolved | Nervous system disorders           | Headache               |
| Comments:   |  |          |                             |  |                                     |                                |                     |                                    |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01EM003, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |                                    |                        |
| Headache  | 27 (0)   | Moderate | Not related                 | Other medical condition or illness: Tension Headaches                  | Dose not changed                    | No                             | Recovered /resolved | Nervous system disorders           | Headache               |
| Comments:   |  |          |                             |  |                                     |                                |                     |                                    |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01EM016, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |                                    |                        |
| Decreased Appetite  | 0 (1)  | Mild     | Related                     | N/A  | Dose not changed                    | No                             | Recovered /resolved | Metabolism and nutrition disorders | Decreased appetite     |

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA <sup>®</sup> Sytem Organ Class                | MedDRA <sup>®</sup> Preferred Term |
|---|--|----------|-----------------------------|---|-------------------------------------|--------------------------------|---------------------|--|------------------------------------|
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01EM016, AE Number: 002</b> |  |          |                             |   |                                     |                                |                     |  |                                    |
| Worsening Vaginal Itching   | 6 (34)   | Mild     | Not related                 | Other medical condition or illness: Vaginal Itching | Dose not changed                    | No                             | Recovered /resolved | Reproductive system and breast disorders             | Vulvovaginal pruritus              |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01EM016, AE Number: 003</b> |  |          |                             |   |                                     |                                |                     |  |                                    |
| Headache  | 8 (12)   | Mild     | Not related                 | Other: stress                                       | Dose not changed                    | No                             | Recovered /resolved | Nervous system disorders                             | Headache                           |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01EM016, AE Number: 004</b> |  |          |                             |   |                                     |                                |                     |  |                                    |
| Lip Bumps   | 21 (7)   | Mild     | Not related                 | Other medical condition or illness: dermatitis      | Dose not changed                    | No                             | Recovered /resolved | Gastrointestinal disorders                           | Lip disorder                       |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01EM020, AE Number: 001</b> |  |          |                             |   |                                     |                                |                     |  |                                    |
| Redness at Vaccine Site   | 12 (3)   | Moderate | Related                     | N/A   | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Injection site erythema            |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                         | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® Sytem Organ Class                       | MedDRA® Preferred Term |
|---|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|---|------------------------|
| Comments: Subject seen today for routine follow up visit. First noted it on 27APR2020. Size was 92mm. |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01HC012, AE Number: 001</b>     |  |          |                             |  |                                     |                                |                     |   |                        |
| Hypertension  | 6 (0)  | Mild     | Not related                 | Study procedure: Failed to repeat blood pressure measurement | Dose not changed                    | No                             | Recovered /resolved | Vascular disorders                              | Hypertension           |
| Comments:   |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01KP037, AE Number: 001</b>     |  |          |                             |  |                                     |                                |                     |   |                        |
| Right Knee Pain   | 2 (0)  | Mild     | Not related                 | Other: inactivity  | Not applicable                      | No                             | Recovered /resolved | Musculoskeletal and connective tissue disorders | Arthralgia             |
| Comments:   |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01KP037, AE Number: 002</b>     |  |          |                             |  |                                     |                                |                     |   |                        |
| Sore Throat   | 24 (3)   | Mild     | Not related                 | Other medical condition or illness: Viral illness            | WD- Drug withdrawn                  | No                             | Recovered /resolved | Respiratory, thoracic and mediastinal disorders | Oropharyngeal pain     |
| Comments:   |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01KP037, AE Number: 003</b>     |  |          |                             |  |                                     |                                |                     |   |                        |

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                    | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                           | MedDRA® Preferred Term  |
|--|--|----------|-----------------------------|---|-------------------------------------|--------------------------------|---------------------|--|-------------------------|
| Vaginal Itching  | 56 (18)  | Mild     | Not related                 | Other medical condition or illness: Fungal infection    | Not applicable                      | No                             | Recovered /resolved | Reproductive system and breast disorders             | Vulvovaginal pruritus   |
| Comments:  |  |          |                             |   |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01KP037, AE Number: 004</b>                    |  |          |                             |   |                                     |                                |                     |  |                         |
| Anal Fissure   | 56 (21)  | Mild     | Not related                 | Other: mechanical pressure from stool                   | Not applicable                      | No                             | Recovered /resolved | Gastrointestinal disorders                           | Anal fissure            |
| Comments: See in UC for perianal pain. Dx with anal fissure. Prescribed lidocaine 2% gel. Improving as of 6/23/2020. |  |          |                             |   |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01KP037, AE Number: 005</b>                    |  |          |                             |   |                                     |                                |                     |  |                         |
| Uti  | 133 (2)  | Mild     | Not related                 | Other medical condition or illness: bacterial infection | Not applicable                      | No                             | Recovered /resolved | Infections and infestations                          | Urinary tract infection |
| Comments:  |  |          |                             |   |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01KP040, AE Number: 001</b>                    |  |          |                             |   |                                     |                                |                     |  |                         |
| Injection Site Redness   | 10 (1)   | Mild     | Related                     | N/A   | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Injection site erythema |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                           | MedDRA® Preferred Term  |
|---|--|----------|-----------------------------|--------------------------------------|-------------------------------------|--------------------------------|---------------------|--|-------------------------|
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01KP041, AE Number: 001</b> |  |          |                             |                                      |                                     |                                |                     |  |                         |
| Vaginal Spotting  | 0 (1)  | Mild     | Related                     | N/A                                  | Dose not changed                    | No                             | Recovered /resolved | Reproductive system and breast disorders             | Vaginal haemorrhage     |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01KP049, AE Number: 001</b> |  |          |                             |                                      |                                     |                                |                     |  |                         |
| Itching at Injection Site   | 7 (4)  | Mild     | Related                     | N/A                                  | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Injection site pruritus |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01KP049, AE Number: 002</b> |  |          |                             |                                      |                                     |                                |                     |  |                         |
| Bradycardia   | 14 (14)  | Mild     | Not related                 | Other: physical conditionin g        | Dose not changed                    | No                             | Recovered /resolved | Cardiac disorders                                    | Bradycardia             |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01KP049, AE Number: 005</b> |  |          |                             |                                      |                                     |                                |                     |  |                         |
| Hypotension Systolic  | 28 (15)  | Mild     | Not related                 | Other: Decreased activity level      | Dose not changed                    | No                             | Recovered /resolved | Vascular disorders                                   | Hypotension             |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                         |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                         | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                      | MedDRA® Preferred Term |
|---|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|---|------------------------|
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 01, Subject ID: CV01KP053, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |   |                        |
| Muscle Strain In Neck   | 11 (7)   | Moderate | Not related                 | Other: sleeping position                                     | Dose not changed                    | No                             | Recovered /resolved | Musculoskeletal and connective tissue disorders | Muscle strain          |
| Comments:   |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01EM003, AE Number: 003</b> |  |          |                             |  |                                     |                                |                     |   |                        |
| Headache  | 23 (0)   | Moderate | Not related                 | Other medical condition or illness: Headache medical history | Not applicable                      | No                             | Recovered /resolved | Nervous system disorders                        | Headache               |
| Comments:   |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01EM020, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |   |                        |
| Abdominal Discomfort  | 26 (10)  | Moderate | Related                     | N/A  | Not applicable                      | No                             | Recovered /resolved | Gastrointestinal disorders                      | Abdominal discomfort   |
| Comments:   |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01HC012, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |   |                        |
| Hypoglycemia  | 7 (7)  | Moderate | Not related                 | Other: decreased PO intake                                   | Not applicable                      | No                             | Recovered /resolved | Metabolism and nutrition disorders              | Hypoglycaemia          |
| Comments:   |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01KP033, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |   |                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® Sytem Organ Class                       | MedDRA® Preferred Term |
|---|--|----------|-----------------------------|--------------------------------------|-------------------------------------|--------------------------------|---------------------|---|------------------------|
| Stomach Ache  | 7 (0)  | Mild     | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | Gastrointestinal disorders                      | Abdominal pain upper   |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01KP036, AE Number: 002</b> |  |          |                             |                                      |                                     |                                |                     |   |                        |
| Muscle Spasms   | 1 (0)  | Moderate | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | Musculoskeletal and connective tissue disorders | Muscle spasms          |
| Comments: in neck and back, spasms cycled over minutes between clench and release.                |  |          |                             |                                      |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01KP036, AE Number: 003</b> |  |          |                             |                                      |                                     |                                |                     |   |                        |
| Loss of Appetite  | 1 (0)  | Moderate | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | Metabolism and nutrition disorders              | Decreased appetite     |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01KP040, AE Number: 002</b> |  |          |                             |                                      |                                     |                                |                     |   |                        |
| Vomiting  | 1 (0)  | Mild     | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | Gastrointestinal disorders                      | Vomiting               |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01KP040, AE Number: 003</b> |  |          |                             |                                      |                                     |                                |                     |   |                        |
| Lightheadedness   | 1 (0)  | Severe   | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | Nervous system disorders                        | Dizziness              |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01KP040, AE Number: 004</b> |  |          |                             |                                      |                                     |                                |                     |   |                        |

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                    | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                           | MedDRA® Preferred Term      |
|---|--|----------|-----------------------------|---|-------------------------------------|--------------------------------|---------------------|--|-----------------------------|
| Syncope   | 1 (0)  | Severe   | Related                     | N/A   | Not applicable                      | No                             | Recovered /resolved | Nervous system disorders                             | Syncope                     |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01KP040, AE Number: 005</b> |  |          |                             |   |                                     |                                |                     |  |                             |
| Bruise at Phlebotomy Site R Arm   | 1 (16)   | Mild     | Not related                 | Other: trauma from blood draw                           | Not applicable                      | No                             | Recovered /resolved | General disorders and administration site conditions | Vessel puncture site bruise |
| Comments: This was from blood draw at urgent care visit, not a study visit, per query.            |  |          |                             |   |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01KP040, AE Number: 006</b> |  |          |                             |   |                                     |                                |                     |  |                             |
| Recurrence of Scintillating Scotomata   | 13 (0)   | Mild     | Related                     | N/A   | Not applicable                      | No                             | Recovered /resolved | Eye disorders  | Scintillating scotoma       |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01KP040, AE Number: 007</b> |  |          |                             |   |                                     |                                |                     |  |                             |
| Epididymitis  | 29 (16)  | Moderate | Not related                 | Other medical condition or illness: Bacterial infection | Not applicable                      | No                             | Recovered /resolved | Infections and infestations                          | Epididymitis                |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01KP041, AE Number: 002</b> |  |          |                             |   |                                     |                                |                     |  |                             |

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                      | MedDRA® Preferred Term |
|---|--|----------|-----------------------------|--------------------------------------|-------------------------------------|--------------------------------|---------------------|---|------------------------|
| Loss of Appetite  | 0 (2)  | Moderate | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | Metabolism and nutrition disorders              | Decreased appetite     |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01KP041, AE Number: 003</b> |  |          |                             |                                      |                                     |                                |                     |   |                        |
| Sweating  | 0 (1)  | Moderate | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | Skin and subcutaneous tissue disorders          | Hyperhidrosis          |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01KP041, AE Number: 004</b> |  |          |                             |                                      |                                     |                                |                     |   |                        |
| Insomnia  | 7 (Ongoing)  | Mild     | Not related                 | Other: situational stress            | Not applicable                      | No                             |                     | Psychiatric disorders                           | Insomnia               |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01KP041, AE Number: 005</b> |  |          |                             |                                      |                                     |                                |                     |   |                        |
| Anxiety   | 1 (11)   | Mild     | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | Psychiatric disorders                           | Anxiety                |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01KP041, AE Number: 006</b> |  |          |                             |                                      |                                     |                                |                     |   |                        |
| Hand Ache   | 8 (0)  | Mild     | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | Musculoskeletal and connective tissue disorders | Pain in extremity      |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01KP049, AE Number: 003</b> |  |          |                             |                                      |                                     |                                |                     |   |                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA <sup>®</sup> System Organ Class               | MedDRA <sup>®</sup> Preferred Term |
|---|--|----------|-----------------------------|--------------------------------------|-------------------------------------|--------------------------------|---------------------|--|------------------------------------|
| Malaise   | 1 (1)  | Moderate | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | General disorders and administration site conditions | Malaise                            |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01KP049, AE Number: 004</b> |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| Night Sweats  | 2 (0)  | Moderate | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | Skin and subcutaneous tissue disorders               | Night sweats                       |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01KP049, AE Number: 006</b> |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| Bradycardia   | 15 (15)  | Mild     | Not related                 | Other: Physical conditionin g        | Not applicable                      | No                             | Recovered /resolved | Cardiac disorders                                    | Bradycardia                        |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 250 µg (18-55 years), Dose #: 02, Subject ID: CV01KP049, AE Number: 007</b> |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| Indigestion   | 14 (13)  | Mild     | Not related                 | Other: Dietary changes               | Not applicable                      | No                             | Recovered /resolved | Gastrointestinal disorders                           | Dyspepsia                          |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 25 µg (56-70 years), Dose #: 01, Subject ID: CV01EM025, AE Number: 001</b>  |  |          |                             |                                      |                                     |                                |                     |  |                                    |

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                  | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome               | MedDRA® System Organ Class                     | MedDRA® Preferred Term  |
|--|--|----------|-----------------------------|---|-------------------------------------|--------------------------------|-----------------------|--|-------------------------|
| Headache   | 27 (0)   | Mild     | Not related                 | Other medical condition or illness: tension headaches | Dose not changed                    | No                             | Recovered /resolved   | Nervous system disorders                       | Headache                |
| Comments:  |  |          |                             |   |                                     |                                |                       |  |                         |
| <b>Vaccination Group: 25 µg (56-70 years), Dose #: 01, Subject ID: CV01EM025, AE Number: 002</b>   |  |          |                             |   |                                     |                                |                       |  |                         |
| Worsening toenail Fungus   | 25 (Ongoing)                                       | Moderate | Not related                 | Other medical condition or illness: Fungal infection  | Dose not changed                    | No                             | Recovering /resolving | Infections and infestations                    | Onychomycosis           |
| Comments: Subject went to MD on 28JUL2020. Updated form to MAAE.   |  |          |                             |   |                                     |                                |                       |  |                         |
| <b>Vaccination Group: 25 µg (56-70 years), Dose #: 01, Subject ID: CV01EM029, AE Number: 001</b>   |  |          |                             |   |                                     |                                |                       |  |                         |
| Worsening of Sciatica  | 5 (1)  | Mild     | Not related                 | Other: Exercise paddle boating                        | Dose not changed                    | No                             | Recovered /resolved   | Nervous system disorders                       | Sciatica                |
| Comments: Subject has pre-existing sciatica pain that occurs occasionally. Subject mentioned worsening of sciatica following paddle boating. |  |          |                             |   |                                     |                                |                       |  |                         |
| <b>Vaccination Group: 25 µg (56-70 years), Dose #: 01, Subject ID: CV01EM029, AE Number: 002</b>   |  |          |                             |   |                                     |                                |                       |  |                         |
| Exposure to Inhaled Irritants  | 12 (0)   | Moderate | Not related                 | Other: exposure to onions                             | Dose not changed                    | No                             | Recovered /resolved   | Injury, poisoning and procedural complications | Exposure via inhalation |
| Comments: Subject went onion picking and developed tearing and rhinorrhea. She took Benadryl with resolution of her symptoms.                |  |          |                             |   |                                     |                                |                       |  |                         |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                   | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                           | MedDRA® Preferred Term  |
|--|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|--|-------------------------|
| <b>Vaccination Group: 25 µg (56-70 years), Dose #: 01, Subject ID: CV01EM030, AE Number: 001</b>   |  |          |                             |  |                                     |                                |                     |  |                         |
| Sore Throat  | 1 (1)  | Mild     | Not related                 | Other medical condition or illness: SEASONAL ALLERGIES | Dose not changed                    | No                             | Recovered /resolved | Respiratory, thoracic and mediastinal disorders      | Oropharyngeal pain      |
| Comments: She has seasonal allergies at part of her past medical history. Her sore throat felt similar to prior seasonal allergy issues that she has had due to high pollen count. |  |          |                             |  |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 25 µg (56-70 years), Dose #: 01, Subject ID: CV01EM041, AE Number: 001</b>   |  |          |                             |  |                                     |                                |                     |  |                         |
| Bruise at Injection Site   | 1 (11)   | Mild     | Not related                 | Study procedure: Vaccine Administration                | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Injection site bruising |
| Comments:  |  |          |                             |  |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 25 µg (56-70 years), Dose #: 01, Subject ID: CV01HC032, AE Number: 001</b>   |  |          |                             |  |                                     |                                |                     |  |                         |
| Bruise at Injection Site   | 0 (4)  | Mild     | Not related                 | Study procedure: vaccination procedure                 | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Injection site bruising |
| Comments:  |  |          |                             |  |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 25 µg (56-70 years), Dose #: 02, Subject ID: CV01EM027, AE Number: 001</b>   |  |          |                             |  |                                     |                                |                     |  |                         |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology         | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome               | MedDRA® Sytem Organ Class                      | MedDRA® Preferred Term |
|--|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|-----------------------|--|------------------------|
| No Appetite  | 1 (1)  | Moderate | Related                     | N/A  | Not applicable                      | No                             | Recovered /resolved   | Metabolism and nutrition disorders             | Decreased appetite     |
| Comments: Combined solicited systemic Symptoms kept subject from eating for > 24 hours.          |  |          |                             |  |                                     |                                |                       |  |                        |
| <b>Vaccination Group: 25 µg (56-70 years), Dose #: 02, Subject ID: CV01EM029, AE Number: 003</b> |  |          |                             |  |                                     |                                |                       |  |                        |
| Worsening of Sciatica  | 56 (39)  | Moderate | Not related                 | Other medical condition or illness: Activity | Not applicable                      | No                             | Recovered /resolved   | Nervous system disorders                       | Sciatica               |
| Comments:  |  |          |                             |  |                                     |                                |                       |  |                        |
| <b>Vaccination Group: 25 µg (56-70 years), Dose #: 02, Subject ID: CV01EM029, AE Number: 004</b> |  |          |                             |  |                                     |                                |                       |  |                        |
| Decreased Bone Density   | 28 (Ongoing)                                       | Moderate | Not related                 | Other medical condition or illness: Aging    | Not applicable                      | No                             | Recovering /resolving | Investigations                                 | Bone density decreased |
| Comments:  |  |          |                             |  |                                     |                                |                       |  |                        |
| <b>Vaccination Group: 25 µg (56-70 years), Dose #: 02, Subject ID: CV01EM030, AE Number: 002</b> |  |          |                             |  |                                     |                                |                       |  |                        |
| Trauma to Arm  | 6 (16)   | Moderate | Not related                 | Other: cat attack                            | Not applicable                      | No                             | Recovered /resolved   | Injury, poisoning and procedural complications | Limb injury            |
| Comments: Bruise and cat scratches on L arm by her own cat which suffers from dementia.          |  |          |                             |  |                                     |                                |                       |  |                        |
| <b>Vaccination Group: 25 µg (56-70 years), Dose #: 02, Subject ID: CV01HC027, AE Number: 001</b> |  |          |                             |  |                                     |                                |                       |  |                        |



**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                   | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome                     | MedDRA® Sytem Organ Class                       | MedDRA® Preferred Term |
|---|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|-----------------------------|---|------------------------|
| Insomnia  | 0 (1)  | Mild     | Related                     | N/A  | Not applicable                      | No                             | Recovered /resolved         | Psychiatric disorders                           | Insomnia               |
| Comments:   |  |          |                             |  |                                     |                                |                             |   |                        |
| <b>Vaccination Group: 25 µg (56-70 years), Dose #: 02, Subject ID: CV01HC032, AE Number: 002</b>  |  |          |                             |  |                                     |                                |                             |   |                        |
| Foot Pain   | 6 (Ongoing)  | Mild     | Not related                 | Other medical condition or illness: plantar fasciitis  | Not applicable                      | No                             | Not recovered /Not resolved | Musculoskeletal and connective tissue disorders | Pain in extremity      |
| Comments:   |  |          |                             |  |                                     |                                |                             |   |                        |
| <b>Vaccination Group: 100 µg (56-70 years), Dose #: 01, Subject ID: CV01EM032, AE Number: 001</b> |  |          |                             |  |                                     |                                |                             |   |                        |
| Nasal Congestion  | 13 (2)   | Moderate | Not related                 | Other medical condition or illness: seasonal allergies | Dose not changed                    | No                             | Recovered /resolved         | Respiratory, thoracic and mediastinal disorders | Nasal congestion       |
| Comments: took pseudoephedrine once, currently much improved minimal residual symptoms            |  |          |                             |  |                                     |                                |                             |   |                        |
| <b>Vaccination Group: 100 µg (56-70 years), Dose #: 01, Subject ID: CV01EM039, AE Number: 001</b> |  |          |                             |  |                                     |                                |                             |   |                        |
| Sore Throat   | 21 (1)   | Mild     | Not related                 | Other: Environmental Exposure                          | Dose not changed                    | No                             | Recovered /resolved         | Respiratory, thoracic and mediastinal disorders | Oropharyngeal pain     |
| Comments:   |  |          |                             |  |                                     |                                |                             |   |                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                    | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® Sytem Organ Class              | MedDRA® Preferred Term |
|---|--|----------|-----------------------------|---|-------------------------------------|--------------------------------|---------------------|--|------------------------|
| <b>Vaccination Group: 100 µg (56-70 years), Dose #: 01, Subject ID: CV01EM045, AE Number: 001</b>   |  |          |                             |   |                                     |                                |                     |  |                        |
| Paronychia  | 2 (13)   | Moderate | Not related                 | Other medical condition or illness: Bacterial Infection | Dose not changed                    | No                             | Recovered /resolved | Infections and infestations            | Paronychia             |
| Comments: Redness & Swelling that developed 25APR2020. This worsened on 26APR2020 and she presented to Urgent Care where she had an incision and drainage performed under local anesthetics (Lidocaine). She was given a dose of Ceftriaxone and discharged on Sulfamethoxazole-Trimethoprim. |  |          |                             |   |                                     |                                |                     |  |                        |
| <b>Vaccination Group: 100 µg (56-70 years), Dose #: 01, Subject ID: CV01EM045, AE Number: 002</b>   |  |          |                             |   |                                     |                                |                     |  |                        |
| Maculopapular Rash  | 9 (21)   | Moderate | Not related                 | Other drug: Sulfamethoxazole-Trimethoprim               | WD- Drug withdrawn                  | No                             | Recovered /resolved | Skin and subcutaneous tissue disorders | Rash maculo-papular    |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                        |
| <b>Vaccination Group: 100 µg (56-70 years), Dose #: 01, Subject ID: CV01EM045, AE Number: 003</b>   |  |          |                             |   |                                     |                                |                     |  |                        |
| Contact Dermatitis  | 111 (26)   | Moderate | Not related                 | Other: Poison Ivy                                       | Not applicable                      | No                             | Recovered /resolved | Skin and subcutaneous tissue disorders | Dermatitis contact     |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                        |
| <b>Vaccination Group: 100 µg (56-70 years), Dose #: 01, Subject ID: CV01HC034, AE Number: 001</b>   |  |          |                             |   |                                     |                                |                     |  |                        |

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology            | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® Sytem Organ Class                      | MedDRA® Preferred Term |
|---|--|----------|-----------------------------|---|-------------------------------------|--------------------------------|---------------------|--|------------------------|
| Systolic Hypertension   | 14 (15)  | Mild     | Not related                 | Other: labile blood pressure                    | Dose not changed                    | No                             | Recovered /resolved | Vascular disorders                             | Systolic hypertension  |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                        |
| <b>Vaccination Group: 100 µg (56-70 years), Dose #: 01, Subject ID: CV01HC038, AE Number: 001</b> |  |          |                             |   |                                     |                                |                     |  |                        |
| Hypoglycemia  | 8 (5)  | Severe   | Not related                 | Other: fasting and vigorous exercise            | Dose not changed                    | No                             | Recovered /resolved | Metabolism and nutrition disorders             | Hypoglycaemia          |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                        |
| <b>Vaccination Group: 100 µg (56-70 years), Dose #: 02, Subject ID: CV01EM023, AE Number: 001</b> |  |          |                             |   |                                     |                                |                     |  |                        |
| Hemorrhoids   | 4 (5)  | Mild     | Not related                 | Other medical condition or illness: hemorrhoids | Not applicable                      | No                             | Recovered /resolved | Gastrointestinal disorders                     | Haemorrhoids           |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                        |
| <b>Vaccination Group: 100 µg (56-70 years), Dose #: 02, Subject ID: CV01EM024, AE Number: 001</b> |  |          |                             |   |                                     |                                |                     |  |                        |
| Bee Sting Skin Reaction   | 27 (4)   | Mild     | Not related                 | Other: Bee sting                                | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications | Arthropod sting        |
| Comments: 1.5 x 1.5 red area on right forehead Red facial bump                                    |  |          |                             |   |                                     |                                |                     |  |                        |
| <b>Vaccination Group: 100 µg (56-70 years), Dose #: 02, Subject ID: CV01HC037, AE Number: 001</b> |  |          |                             |   |                                     |                                |                     |  |                        |

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                    | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                     | MedDRA® Preferred Term |
|---|--|----------|-----------------------------|---|-------------------------------------|--------------------------------|---------------------|--|------------------------|
| Vertigo   | 1 (0)  | Mild     | Related                     | N/A   | Not applicable                      | No                             | Recovered /resolved | Ear and labyrinth disorders                    | Vertigo                |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                        |
| <b>Vaccination Group: 100 µg (56-70 years), Dose #: 02, Subject ID: CV01HC037, AE Number: 002</b> |  |          |                             |   |                                     |                                |                     |  |                        |
| Dizziness   | 5 (0)  | Mild     | Not related                 | Other: strenuous exercise and dehydration               | Not applicable                      | No                             | Recovered /resolved | Nervous system disorders                       | Dizziness              |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                        |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 01, Subject ID: CV01KP059, AE Number: 001</b>    |  |          |                             |   |                                     |                                |                     |  |                        |
| Sunburn   | 4 (9)  | Mild     | Not related                 | Other: Excessive sun exposure                           | Dose not changed                    | No                             | Recovered /resolved | Injury, poisoning and procedural complications | Sunburn                |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                        |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 01, Subject ID: CV01KP059, AE Number: 002</b>    |  |          |                             |   |                                     |                                |                     |  |                        |
| Pustule   | 20 (35)  | Mild     | Not related                 | Other medical condition or illness: Bacterial infection | Dose not changed                    | No                             | Recovered /resolved | Infections and infestations                    | Pustule                |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                        |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 01, Subject ID: CV01KP060, AE Number: 001</b>    |  |          |                             |   |                                     |                                |                     |  |                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology               | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                      | MedDRA® Preferred Term |
|--|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|---|------------------------|
| Bilateral Ankle Swelling   | 2 (1)  | Mild     | Not related                 | Other: Wore a constrictive pair of new socks       | Dose not changed                    | No                             | Recovered /resolved | Musculoskeletal and connective tissue disorders | Joint swelling         |
| Comments:  |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 01, Subject ID: CV01KP060, AE Number: 004</b> |  |          |                             |  |                                     |                                |                     |   |                        |
| Burn L Forearm   | 28 (35)  | Mild     | Not related                 | Other medical condition or illness: Thermal trauma | Dose not changed                    | No                             | Recovered /resolved | Injury, poisoning and procedural complications  | Thermal burn           |
| Comments:  |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 01, Subject ID: CV01KP061, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |   |                        |
| Lightheadedness  | 0 (0)  | Mild     | Related                     | N/A  | Dose not changed                    | No                             | Recovered /resolved | Nervous system disorders                        | Dizziness              |
| Comments:  |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 01, Subject ID: CV01KP061, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |   |                        |
| Night Sweats   | 2 (2)  | Mild     | Related                     | N/A  | Dose not changed                    | No                             | Recovered /resolved | Skin and subcutaneous tissue disorders          | Night sweats           |
| Comments:  |  |          |                             |  |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 01, Subject ID: CV01KP061, AE Number: 003</b> |  |          |                             |  |                                     |                                |                     |   |                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® Sytem Organ Class                            | MedDRA® Preferred Term     |
|--|--|----------|-----------------------------|--------------------------------------|-------------------------------------|--------------------------------|---------------------|--|----------------------------|
| Anxiety  | 4 (0)  | Mild     | Related                     | N/A                                  | Dose not changed                    | No                             | Recovered /resolved | Psychiatric disorders                                | Anxiety                    |
| Comments:  |  |          |                             |                                      |                                     |                                |                     |  |                            |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 01, Subject ID: CV01KP062, AE Number: 001</b> |  |          |                             |                                      |                                     |                                |                     |  |                            |
| Increased Energy   | 0 (3)  | Mild     | Related                     | N/A                                  | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Energy increased           |
| Comments:  |  |          |                             |                                      |                                     |                                |                     |  |                            |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 01, Subject ID: CV01KP062, AE Number: 002</b> |  |          |                             |                                      |                                     |                                |                     |  |                            |
| Lightheadedness  | 28 (0)   | Mild     | Not related                 | Study procedure: Blood draw          | Dose not changed                    | No                             | Recovered /resolved | Nervous system disorders                             | Dizziness                  |
| Comments:  |  |          |                             |                                      |                                     |                                |                     |  |                            |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 01, Subject ID: CV01KP063, AE Number: 001</b> |  |          |                             |                                      |                                     |                                |                     |  |                            |
| L Upper torso Musculoskeletal Pain   | 1 (12)   | Moderate | Not related                 | Other: Bicycle accident              | Dose not changed                    | No                             | Recovered /resolved | Musculoskeletal and connective tissue disorders      | Musculoskeletal chest pain |
| Comments:  |  |          |                             |                                      |                                     |                                |                     |  |                            |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 01, Subject ID: CV01KP063, AE Number: 002</b> |  |          |                             |                                      |                                     |                                |                     |  |                            |
| Abrasion to L Elbow  | 1 (14)   | Mild     | Not related                 | Other: Bicycle accident              | Dose not changed                    | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Skin abrasion              |
| Comments:  |  |          |                             |                                      |                                     |                                |                     |  |                            |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology      | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® Sytem Organ Class                            | MedDRA® Preferred Term  |
|--|--|----------|-----------------------------|---|-------------------------------------|--------------------------------|---------------------|--|-------------------------|
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 01, Subject ID: CV01KP066, AE Number: 001</b> |  |          |                             |   |                                     |                                |                     |  |                         |
| Itching Lateral R Clavicle   | 0 (0)  | Mild     | Related                     | N/A                                       | Dose not changed                    | No                             | Recovered /resolved | Skin and subcutaneous tissue disorders               | Pruritus                |
| Comments: 5-10 minute duration   |  |          |                             |   |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 01, Subject ID: CV01KP068, AE Number: 001</b> |  |          |                             |   |                                     |                                |                     |  |                         |
| L Upper Arm Abrasion   | 0 (10)   | Mild     | Not related                 | Other: Scratched arm while doing yardwork | Dose not changed                    | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Skin abrasion           |
| Comments:  |  |          |                             |   |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 01, Subject ID: CV01KP068, AE Number: 002</b> |  |          |                             |   |                                     |                                |                     |  |                         |
| Bruise at Injection Site   | 2 (10)   | Mild     | Not related                 | Study procedure: Needle trauma            | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Injection site bruising |
| Comments:  |  |          |                             |   |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 01, Subject ID: CV01KP068, AE Number: 003</b> |  |          |                             |   |                                     |                                |                     |  |                         |
| Tick Bite  | 3 (85)   | Mild     | Not related                 | Other: Insect bite                        | Dose not changed                    | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Arthropod bite          |
| Comments:  |  |          |                             |   |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 01, Subject ID: CV01KP068, AE Number: 004</b> |  |          |                             |   |                                     |                                |                     |  |                         |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology                | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                      | MedDRA® Preferred Term |
|--|--|----------|-----------------------------|---|-------------------------------------|--------------------------------|---------------------|---|------------------------|
| Exacerbation of Arthritis  | 27 (62)  | Moderate | Not related                 | Other: overuse                                      | Dose not changed                    | No                             | Recovered /resolved | Musculoskeletal and connective tissue disorders | Arthritis              |
| Comments: Pts states has had for 2 yrs and increased and decreased with activity. Much worse than previous events, started wearing brace (from MD sister). 6/10/20 Subject states condition remains. Has phone visit with provider on 6/11/20 6/16/20 MAAE as of 6/12/20 - video appointment with occupational therapy |  |          |                             |   |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 01, Subject ID: CV01KP072, AE Number: 001</b>   |  |          |                             |   |                                     |                                |                     |   |                        |
| Disturbed Sleep Cycle  | 0 (1)  | Mild     | Related                     | N/A   | Dose not changed                    | No                             | Recovered /resolved | Psychiatric disorders                           | Sleep disorder         |
| Comments: At V7 phone call, subject reported sleep cycle disturbance after first vaccine but had not previously reported.  |  |          |                             |   |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 02, Subject ID: CV01KP059, AE Number: 003</b>   |  |          |                             |   |                                     |                                |                     |   |                        |
| Fingertip Puncture   | 10 (8)   | Mild     | Not related                 | Other: Trauma                                       | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications  | Limb injury            |
| Comments: <5 mm puncture wound to R 5th fingertip.   |  |          |                             |   |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 02, Subject ID: CV01KP060, AE Number: 005</b>   |  |          |                             |   |                                     |                                |                     |   |                        |
| Excoriation  | 8 (1)  | Mild     | Not related                 | Other: Scratching where adhesive bandage was placed | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications  | Skin abrasion          |
| Comments:  |  |          |                             |   |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 02, Subject ID: CV01KP062, AE Number: 003</b>   |  |          |                             |   |                                     |                                |                     |   |                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                           | MedDRA® Preferred Term  |
|--|--|----------|-----------------------------|--------------------------------------|-------------------------------------|--------------------------------|---------------------|--|-------------------------|
| Increased Energy   | 0 (0)  | Mild     | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | General disorders and administration site conditions | Energy increased        |
| Comments:  |  |          |                             |                                      |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 02, Subject ID: CV01KP062, AE Number: 004</b> |  |          |                             |                                      |                                     |                                |                     |  |                         |
| Decreased Peripheral Vision  | 0 (0)  | Mild     | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | Nervous system disorders                             | Visual field defect     |
| Comments:  |  |          |                             |                                      |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 02, Subject ID: CV01KP062, AE Number: 005</b> |  |          |                             |                                      |                                     |                                |                     |  |                         |
| Itching at Injection Site  | 2 (0)  | Mild     | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | General disorders and administration site conditions | Injection site pruritus |
| Comments:  |  |          |                             |                                      |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 02, Subject ID: CV01KP062, AE Number: 006</b> |  |          |                             |                                      |                                     |                                |                     |  |                         |
| Fatigue  | 11 (13)  | Mild     | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | General disorders and administration site conditions | Fatigue                 |
| Comments:  |  |          |                             |                                      |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 02, Subject ID: CV01KP063, AE Number: 003</b> |  |          |                             |                                      |                                     |                                |                     |  |                         |

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event  | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® Sytem Organ Class                       | MedDRA® Preferred Term |
|--|--|----------|-----------------------------|--------------------------------------|-------------------------------------|--------------------------------|---------------------|---|------------------------|
| Skin Irritation  | 0 (0)  | Mild     | Not related                 | Other: irritation from shirt fabric  | Dose not changed                    | No                             | Recovered /resolved | Skin and subcutaneous tissue disorders          | Skin irritation        |
| Comments:  |  |          |                             |                                      |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 02, Subject ID: CV01KP065, AE Number: 001</b>   |  |          |                             |                                      |                                     |                                |                     |   |                        |
| Left Triceps Tightness   | 1 (2)  | Mild     | Not related                 | Other: Muscle overuse                | Not applicable                      | No                             | Recovered /resolved | Musculoskeletal and connective tissue disorders | Muscle tightness       |
| Comments:  |  |          |                             |                                      |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 02, Subject ID: CV01KP065, AE Number: 002</b>   |  |          |                             |                                      |                                     |                                |                     |   |                        |
| Post Operative Pain  | 16 (10)  | Mild     | Not related                 | Other: scheduled hernia surgery      | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications  | Procedural pain        |
| Comments: Elective umbilical hernia repair on 06/17/2020, outpatient. Previously scheduled to be done prior to enrollment and delayed due to pandemic. No change in severity or nature of the hernia between enrollment and procedure to repair. |  |          |                             |                                      |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 02, Subject ID: CV01KP072, AE Number: 002</b>   |  |          |                             |                                      |                                     |                                |                     |   |                        |
| Disturbed Sleep Cycle  | 1 (1)  | Mild     | Related                     | N/A                                  | Not applicable                      | No                             | Recovered /resolved | Psychiatric disorders                           | Sleep disorder         |
| Comments:  |  |          |                             |                                      |                                     |                                |                     |   |                        |
| <b>Vaccination Group: 25 µg (≥71 years), Dose #: 02, Subject ID: CV01KP072, AE Number: 003</b>   |  |          |                             |                                      |                                     |                                |                     |   |                        |

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology           | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class                           | MedDRA® Preferred Term      |
|---|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|--|-----------------------------|
| Bradycardia   | 28 (56)  | Mild     | Not related                 | Other: physical conditionin g                  | Not applicable                      | No                             | Recovered /resolved | Cardiac disorders                                    | Bradycardia                 |
| Comments:   |  |          |                             |  |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 01, Subject ID: CV01KP067, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |  |                             |
| Dermatitis  | 0 (10)   | Mild     | Not related                 | Other: Reaction to adhesive on tape            | Dose not changed                    | No                             | Recovered /resolved | Skin and subcutaneous tissue disorders               | Dermatitis                  |
| Comments:   |  |          |                             |  |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 01, Subject ID: CV01KP071, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |  |                             |
| Bruise at Injection Site  | 0 (17)   | Mild     | Not related                 | Study procedure: Needle trauma from vaccine    | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Injection site bruising     |
| Comments:   |  |          |                             |  |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 01, Subject ID: CV01KP071, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |  |                             |
| Bruise at Blood Draw Site   | 0 (9)  | Mild     | Not related                 | Study procedure: Needle trauma from phlebotomy | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Vessel puncture site bruise |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology           | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA <sup>®</sup> System Organ Class               | MedDRA <sup>®</sup> Preferred Term |
|---|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|--|------------------------------------|
| Comments:   |  |          |                             |  |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 01, Subject ID: CV01KP071, AE Number: 003</b> |  |          |                             |  |                                     |                                |                     |  |                                    |
| Bruise at Blood Draw Site   | 27 (78)  | Mild     | Not related                 | Study procedure: phlebotomy trauma from needle | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Vessel puncture site bruise        |
| Comments:   |  |          |                             |  |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 01, Subject ID: CV01KP077, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |  |                                    |
| Erythema Distal And Medial to Injection Site  | 9 (7)  | Mild     | Related                     | N/A  | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Injection site erythema            |
| Comments: 50 mm faint erythema present at V5  |  |          |                             |  |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 01, Subject ID: CV01KP078, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |  |                                    |
| Bruise at Blood Draw Site   | 3 (1)  | Mild     | Not related                 | Study procedure: Needle trauma from phlebotomy | Dose not changed                    | No                             | Recovered /resolved | General disorders and administration site conditions | Vessel puncture site bruise        |
| Comments:   |  |          |                             |  |                                     |                                |                     |  |                                    |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 02, Subject ID: CV01KP064, AE Number: 001</b> |  |          |                             |  |                                     |                                |                     |  |                                    |

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology     | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA <sup>®</sup> System Organ Class          | MedDRA <sup>®</sup> Preferred Term |
|---|--|----------|-----------------------------|--|-------------------------------------|--------------------------------|---------------------|---|------------------------------------|
| Systolic Hypertension   | 14 (14)  | Mild     | Not related                 | Other: strenuous exercise prior to visit | Not applicable                      | No                             | Recovered /resolved | Vascular disorders                              | Systolic hypertension              |
| Comments:   |  |          |                             |  |                                     |                                |                     |   |                                    |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 02, Subject ID: CV01KP064, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |   |                                    |
| Muscle Soreness   | 27 (0)   | Mild     | Not related                 | Other: overuse                           | Not applicable                      | No                             | Recovered /resolved | Musculoskeletal and connective tissue disorders | Myalgia                            |
| Comments:   |  |          |                             |  |                                     |                                |                     |   |                                    |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 02, Subject ID: CV01KP067, AE Number: 002</b> |  |          |                             |  |                                     |                                |                     |   |                                    |
| Chipped tooth   | 3 (76)   | Mild     | Not related                 | Other: Weakened enamel                   | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications  | Tooth fracture                     |
| Comments:   |  |          |                             |  |                                     |                                |                     |   |                                    |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 02, Subject ID: CV01KP067, AE Number: 003</b> |  |          |                             |  |                                     |                                |                     |   |                                    |
| Blister   | 2 (2)  | Mild     | Not related                 | Other: long periods of time exercising   | Not applicable                      | No                             | Recovered /resolved | Skin and subcutaneous tissue disorders          | Blister                            |
| Comments:   |  |          |                             |  |                                     |                                |                     |   |                                    |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 02, Subject ID: CV01KP067, AE Number: 004</b> |  |          |                             |  |                                     |                                |                     |   |                                    |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology      | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® Sytem Organ Class                            | MedDRA® Preferred Term      |
|---|--|----------|-----------------------------|---|-------------------------------------|--------------------------------|---------------------|--|-----------------------------|
| Bruise at Blood Draw Site   | 7 (16)   | Mild     | Not related                 | Study procedure: Phlebotomy needle trauma | Not applicable                      | No                             | Recovered /resolved | General disorders and administration site conditions | Vessel puncture site bruise |
| Comments: 6/30/ Bruise resolved per subject on 6/25/20  |  |          |                             |   |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 02, Subject ID: CV01KP067, AE Number: 005</b> |  |          |                             |   |                                     |                                |                     |  |                             |
| Left Knee Bruise  | 15 (14)  | Mild     | Not related                 | Other: trauma                             | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Contusion                   |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 02, Subject ID: CV01KP067, AE Number: 006</b> |  |          |                             |   |                                     |                                |                     |  |                             |
| Right Knee Abrasion   | 23 (14)  | Mild     | Not related                 | Other: fall                               | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Skin abrasion               |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 02, Subject ID: CV01KP067, AE Number: 007</b> |  |          |                             |   |                                     |                                |                     |  |                             |
| Right Forearm Bruise  | 23 (14)  | Mild     | Not related                 | Other: fall                               | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Contusion                   |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                             |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 02, Subject ID: CV01KP071, AE Number: 004</b> |  |          |                             |   |                                     |                                |                     |  |                             |
| Abrasions   | 27 (2)   | Mild     | Not related                 | Other: trauma from thorns                 | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications       | Skin abrasion               |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology          | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® Sytem Organ Class                      | MedDRA® Preferred Term  |
|---|--|----------|-----------------------------|---|-------------------------------------|--------------------------------|---------------------|--|-------------------------|
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 02, Subject ID: CV01KP073, AE Number: 001</b> |  |          |                             |   |                                     |                                |                     |  |                         |
| Dizziness   | 0 (1)  | Mild     | Related                     | N/A   | Not applicable                      | No                             | Recovered /resolved | Nervous system disorders                       | Dizziness               |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 02, Subject ID: CV01KP073, AE Number: 002</b> |  |          |                             |   |                                     |                                |                     |  |                         |
| Bruise  | 0 (9)  | Mild     | Not related                 | Study procedure: Blood draw                   | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications | Contusion               |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 02, Subject ID: CV01KP073, AE Number: 003</b> |  |          |                             |   |                                     |                                |                     |  |                         |
| Skin Rash   | 11 (2)   | Mild     | Not related                 | Other: use of over the counter cosmetic cream | Not applicable                      | No                             | Recovered /resolved | Skin and subcutaneous tissue disorders         | Rash                    |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                         |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 02, Subject ID: CV01KP077, AE Number: 002</b> |  |          |                             |   |                                     |                                |                     |  |                         |
| Uti   | 58 (3)   | Mild     | Not related                 | Other medical condition or illness: infection | Not applicable                      | No                             | Recovered /resolved | Infections and infestations                    | Urinary tract infection |
| Comments:   |  |          |                             |   |                                     |                                |                     |  |                         |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| Adverse Event   | No. of Days Post Associated Vaccination (Duration) | Severity | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to AE | Outcome             | MedDRA® System Organ Class  | MedDRA® Preferred Term  |
|---|--|----------|-----------------------------|--------------------------------------|-------------------------------------|--------------------------------|---------------------|---|-------------------------|
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 02, Subject ID: CV01KP078, AE Number: 002</b> |  |          |                             |                                      |                                     |                                |                     |   |                         |
| Bradycardia   | 29 (Ongoing)                                       | Mild     | Not related                 | Other: physical conditionin g        | Not applicable                      | No                             |                     | Cardiac disorders   | Bradycardia             |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |   |                         |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 02, Subject ID: CV01KP081, AE Number: 001</b> |  |          |                             |                                      |                                     |                                |                     |   |                         |
| Irritant Contact Dermatitis   | 0 (22)   | Mild     | Not related                 | Other drug: Efudex                   | Not applicable                      | No                             | Recovered /resolved | Skin and subcutaneous tissue disorders                              | Dermatitis contact      |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |   |                         |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 02, Subject ID: CV01KP081, AE Number: 002</b> |  |          |                             |                                      |                                     |                                |                     |   |                         |
| Abrasion  | 13 (9)   | Mild     | Not related                 | Other: trauma                        | Not applicable                      | No                             | Recovered /resolved | Injury, poisoning and procedural complications                      | Skin abrasion           |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |   |                         |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 02, Subject ID: CV01KP081, AE Number: 003</b> |  |          |                             |                                      |                                     |                                |                     |   |                         |
| Squamous Cell Carcinoma   | 79 (0)   | Mild     | Not related                 | Other: Cell growth                   | Not applicable                      | No                             | Recovered /resolved | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Squamous cell carcinoma |
| Comments:   |  |          |                             |                                      |                                     |                                |                     |   |                         |
| <b>Vaccination Group: 100 µg (≥71 years), Dose #: 02, Subject ID: CV01KP085, AE Number: 001</b> |  |          |                             |                                      |                                     |                                |                     |   |                         |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix B (continued)**  
**Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events**

| <b>Adverse Event</b> | <b>No. of Days Post Associated Vaccination (Duration)</b> | <b>Severity</b> | <b>Relationship to Vaccination</b> | <b>If Not Related, Alternative Etiology</b> | <b>Action Taken with Study Vaccination</b> | <b>Subject Discontinued Due to AE</b> | <b>Outcome</b>      | <b>MedDRA® System Organ Class</b>      | <b>MedDRA® Preferred Term</b> |
|----------------------|---|-----------------|------------------------------------|---|--|---------------------------------------|---------------------|--|-------------------------------|
| Night Sweats         | 1 (0)   | Mild            | Related                            | N/A   | Not applicable                             | No                                    | Recovered /resolved | Skin and subcutaneous tissue disorders | Night sweats                  |
| Comments:            |   |                 |                                    |   |  |                                       |                     |  |                               |

### APPENDIX C1: Solicited Systemic Events

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea |
|------------|-------------------------|-------------|---------------|-------------|------------|--------------|----------|----------|------------|----------|--------|
| CV01EM003  | 250 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01EM003  | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01EM003  | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.4       | None         | None     | None     | None       | None     | None   |
| CV01EM003  | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.2       | None         | None     | None     | None       | None     | None   |
| CV01EM003  | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.4       | None         | None     | None     | None       | None     | None   |
| CV01EM003  | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.6       | None         | None     | None     | None       | None     | None   |
| CV01EM003  | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.4       | None         | None     | None     | None       | None     | None   |
| CV01EM003  | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.3       | None         | None     | None     | None       | None     | None   |
| CV01EM003  | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.3       | None         | None     | None     | None       | None     | None   |
| CV01EM003  | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.6       | None         | None     | None     | None       | None     | None   |
| CV01EM003  | 250 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01EM003  | 250 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01EM003  | 250 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.5       | Moderate     | Moderate | Moderate | Mild       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C)  | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|-------------|--------------|----------|----------|------------|----------|--------|
| CV01EM003  | 250 µg (18-55 years) | 02          | Day 2         | MA          | 38.3 (Mild) | Moderate     | Moderate | Moderate | Mild       | Mild     | None   |
| CV01EM003  | 250 µg (18-55 years) | 02          | Day 3         | MA          | 36.1        | None         | None     | None     | None       | None     | None   |
| CV01EM003  | 250 µg (18-55 years) | 02          | Day 4         | MA          | 36.3        | None         | None     | None     | None       | None     | None   |
| CV01EM003  | 250 µg (18-55 years) | 02          | Day 5         | MA          | 36.7        | None         | None     | None     | None       | None     | None   |
| CV01EM003  | 250 µg (18-55 years) | 02          | Day 6         | MA          | 36.4        | None         | None     | None     | None       | None     | None   |
| CV01EM003  | 250 µg (18-55 years) | 02          | Day 7         | MA          | 36.6        | None         | None     | None     | None       | None     | None   |
| CV01EM003  | 250 µg (18-55 years) | 02          | Day 8         | MA          | 36.4        | None         | None     | None     | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 01          | Pre-Dose      | Clinic      | N/A         | None         | None     | None     | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | N/A         | None         | None     | None     | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 01          | Day 1         | MA          | 36.7        | None         | None     | None     | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 01          | Day 2         | MA          | 36.7        | None         | None     | None     | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 01          | Day 3         | MA          | 36.5        | None         | None     | None     | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 01          | Day 4         | MA          | 36.8        | None         | None     | None     | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 01          | Day 5         | MA          | 36.7        | None         | None     | None     | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C)  | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|-------------|--------------|---------|---------|------------|----------|--------|
| CV01EM004  | 100 µg (18-55 years) | 01          | Day 6         | MA          | 36.6        | None         | None    | None    | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 01          | Day 7         | MA          | 37          | None         | None    | None    | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 01          | Day 8         | MA          | 36.9        | None         | None    | None    | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 02          | Day 1         | MA          | 36.6        | None         | None    | None    | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 02          | Day 2         | MA          | 38.3 (Mild) | Mild         | Mild    | None    | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 02          | Day 3         | MA          | 37.1        | None         | None    | None    | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 02          | Day 4         | MA          | 36.6        | None         | None    | None    | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 02          | Day 5         | MA          | 36.5        | None         | None    | None    | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 02          | Day 6         | MA          | 36.5        | None         | None    | None    | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 02          | Day 7         | MA          | 36.6        | None         | None    | None    | None       | None     | None   |
| CV01EM004  | 100 µg (18-55 years) | 02          | Day 8         | MA          | 36.7        | None         | None    | None    | None       | None     | None   |
| CV01EM005  | 100 µg (18-55 years) | 01          | Pre-Dose      | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia  | Arthralgia | Headache | Nausea   |
|------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|----------|------------|----------|----------|
| CV01EM005  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None     | None       | None     | None     |
| CV01EM005  | 100 µg (18-55 years) | 01          | Day 1         | MA          | 36.5       | None         | None    | None     | None       | None     | None     |
| CV01EM005  | 100 µg (18-55 years) | 01          | Day 2         | MA          | 36.6       | None         | None    | None     | None       | None     | None     |
| CV01EM005  | 100 µg (18-55 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None     | None       | None     | None     |
| CV01EM005  | 100 µg (18-55 years) | 01          | Day 4         | MA          | 37         | None         | None    | None     | None       | None     | None     |
| CV01EM005  | 100 µg (18-55 years) | 01          | Day 5         | MA          | 36.9       | None         | None    | None     | None       | None     | None     |
| CV01EM005  | 100 µg (18-55 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None     | None       | None     | None     |
| CV01EM005  | 100 µg (18-55 years) | 01          | Day 7         | MA          | 37         | None         | None    | None     | None       | None     | None     |
| CV01EM005  | 100 µg (18-55 years) | 01          | Day 8         | MA          | 36.4       | None         | None    | None     | None       | None     | None     |
| CV01EM005  | 100 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None     | None       | None     | None     |
| CV01EM005  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None     | None       | None     | None     |
| CV01EM005  | 100 µg (18-55 years) | 02          | Day 1         | MA          | 36.4       | None         | None    | None     | None       | None     | Moderate |
| CV01EM005  | 100 µg (18-55 years) | 02          | Day 2         | MA          | 37.3       | Mild         | None    | Moderate | None       | None     | None     |
| CV01EM005  | 100 µg (18-55 years) | 02          | Day 3         | MA          | 36.3       | None         | None    | None     | None       | None     | None     |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01EM005  | 100 µg (18-55 years) | 02          | Day 4         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01EM005  | 100 µg (18-55 years) | 02          | Day 5         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01EM005  | 100 µg (18-55 years) | 02          | Day 6         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01EM005  | 100 µg (18-55 years) | 02          | Day 7         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01EM005  | 100 µg (18-55 years) | 02          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 01          | Day 1         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 01          | Day 2         | MA          | 36.9       | None         | None    | Mild    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 01          | Day 4         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 01          | Day 5         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 01          | Day 7         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C)      | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|-----------------|--------------|----------|---------|------------|----------|--------|
| CV01EM007  | 100 µg (18-55 years) | 01          | Day 8         | MA          | 36.5            | None         | None     | None    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A             | None         | None     | None    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A             | None         | None     | None    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 02          | Day 1         | MA          | 36.5            | None         | None     | None    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 02          | Day 2         | MA          | 38.6 (Moderate) | Mild         | Moderate | Mild    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 02          | Day 3         | MA          | 37.4            | None         | None     | None    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 02          | Day 4         | MA          | 37              | None         | None     | None    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 02          | Day 5         | MA          | 36.7            | None         | None     | None    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 02          | Day 6         | MA          | 36.9            | None         | None     | None    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 02          | Day 7         | MA          | 36.7            | None         | None     | None    | None       | None     | None   |
| CV01EM007  | 100 µg (18-55 years) | 02          | Day 8         | MA          | 36.9            | None         | None     | None    | None       | None     | None   |
| CV01EM009  | 100 µg (18-55 years) | 01          | Pre-Dose      | Clinic      | N/A             | None         | None     | None    | None       | None     | None   |
| CV01EM009  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | N/A             | None         | None     | None    | None       | None     | None   |
| CV01EM009  | 100 µg (18-55 years) | 01          | Day 1         | MA          | 37              | None         | None     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C)  | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|-------------|--------------|----------|----------|------------|----------|--------|
| CV01EM009  | 100 µg (18-55 years) | 01          | Day 2         | MA          | 36.8        | None         | None     | None     | None       | None     | None   |
| CV01EM009  | 100 µg (18-55 years) | 01          | Day 3         | MA          | 36.6        | None         | None     | None     | None       | None     | None   |
| CV01EM009  | 100 µg (18-55 years) | 01          | Day 4         | MA          | 36.8        | None         | None     | None     | None       | None     | None   |
| CV01EM009  | 100 µg (18-55 years) | 01          | Day 5         | MA          | 37          | None         | None     | None     | None       | None     | None   |
| CV01EM009  | 100 µg (18-55 years) | 01          | Day 6         | MA          | 36.6        | None         | None     | None     | None       | None     | None   |
| CV01EM009  | 100 µg (18-55 years) | 01          | Day 7         | MA          | 36.5        | None         | None     | None     | None       | None     | None   |
| CV01EM009  | 100 µg (18-55 years) | 01          | Day 8         | MA          | 36.8        | None         | None     | None     | None       | None     | None   |
| CV01EM009  | 100 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A         | None         | None     | None     | None       | None     | None   |
| CV01EM009  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A         | None         | None     | None     | None       | None     | None   |
| CV01EM009  | 100 µg (18-55 years) | 02          | Day 1         | MA          | 36.5        | None         | None     | None     | None       | None     | None   |
| CV01EM009  | 100 µg (18-55 years) | 02          | Day 2         | MA          | 38.1 (Mild) | Moderate     | Moderate | Moderate | None       | Moderate | None   |
| CV01EM009  | 100 µg (18-55 years) | 02          | Day 3         | MA          | 36.6        | None         | None     | None     | None       | None     | None   |
| CV01EM009  | 100 µg (18-55 years) | 02          | Day 4         | MA          | 36.4        | None         | None     | None     | None       | None     | None   |
| CV01EM009  | 100 µg (18-55 years) | 02          | Day 5         | MA          | 36.5        | None         | None     | None     | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01EM009  | 100 µg (18-55 years) | 02          | Day 6         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01EM009  | 100 µg (18-55 years) | 02          | Day 7         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01EM009  | 100 µg (18-55 years) | 02          | Day 8         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01EM010  | 100 µg (18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM010  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM010  | 100 µg (18-55 years) | 01          | Day 1         | MA          | 37.3       | None         | Mild    | None    | None       | None     | None   |
| CV01EM010  | 100 µg (18-55 years) | 01          | Day 2         | MA          | 37.6       | None         | Mild    | None    | None       | Mild     | None   |
| CV01EM010  | 100 µg (18-55 years) | 01          | Day 3         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01EM010  | 100 µg (18-55 years) | 01          | Day 4         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01EM010  | 100 µg (18-55 years) | 01          | Day 5         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01EM010  | 100 µg (18-55 years) | 01          | Day 6         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01EM010  | 100 µg (18-55 years) | 01          | Day 7         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01EM010  | 100 µg (18-55 years) | 01          | Day 8         | MA          | 37.4       | None         | None    | None    | None       | None     | None   |
| CV01EM010  | 100 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|--------|
| CV01EM010  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01EM010  | 100 µg (18-55 years) | 02          | Day 1         | MA          | 37.6       | None         | Mild     | None    | None       | None     | None   |
| CV01EM010  | 100 µg (18-55 years) | 02          | Day 2         | MA          | 37.6       | None         | Moderate | None    | None       | Mild     | None   |
| CV01EM010  | 100 µg (18-55 years) | 02          | Day 3         | MA          | 36.9       | None         | Mild     | None    | None       | None     | None   |
| CV01EM010  | 100 µg (18-55 years) | 02          | Day 4         | MA          | 37.1       | None         | None     | None    | None       | None     | None   |
| CV01EM010  | 100 µg (18-55 years) | 02          | Day 5         | MA          | 37         | None         | None     | None    | None       | None     | None   |
| CV01EM010  | 100 µg (18-55 years) | 02          | Day 6         | MA          | 37.1       | None         | None     | None    | None       | None     | None   |
| CV01EM010  | 100 µg (18-55 years) | 02          | Day 7         | MA          | 37.1       | None         | None     | None    | None       | None     | None   |
| CV01EM010  | 100 µg (18-55 years) | 02          | Day 8         | MA          | 37         | None         | None     | None    | None       | None     | None   |
| CV01EM012  | 100 µg (18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01EM012  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01EM012  | 100 µg (18-55 years) | 01          | Day 1         | MA          | 36.9       | None         | None     | None    | None       | None     | None   |
| CV01EM012  | 100 µg (18-55 years) | 01          | Day 2         | MA          | 36.4       | None         | None     | None    | None       | None     | None   |
| CV01EM012  | 100 µg (18-55 years) | 01          | Day 3         | MA          | 36.9       | None         | None     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C)  | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|-------------|--------------|---------|---------|------------|----------|--------|
| CV01EM012  | 100 µg (18-55 years) | 01          | Day 4         | MA          | 36.8        | None         | None    | None    | None       | None     | None   |
| CV01EM012  | 100 µg (18-55 years) | 01          | Day 5         | MA          | 36.6        | None         | None    | None    | None       | None     | None   |
| CV01EM012  | 100 µg (18-55 years) | 01          | Day 6         | MA          | 36.4        | None         | None    | None    | None       | None     | None   |
| CV01EM012  | 100 µg (18-55 years) | 01          | Day 7         | MA          | 36.8        | None         | None    | None    | Moderate   | None     | None   |
| CV01EM012  | 100 µg (18-55 years) | 01          | Day 8         | MA          | 36.4        | None         | None    | None    | None       | None     | None   |
| CV01EM012  | 100 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01EM012  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01EM012  | 100 µg (18-55 years) | 02          | Day 1         | MA          | 36.7        | None         | None    | None    | None       | None     | None   |
| CV01EM012  | 100 µg (18-55 years) | 02          | Day 2         | MA          | 38.2 (Mild) | None         | None    | None    | Mild       | Moderate | Mild   |
| CV01EM012  | 100 µg (18-55 years) | 02          | Day 3         | MA          | 36.8        | None         | None    | None    | None       | None     | None   |
| CV01EM012  | 100 µg (18-55 years) | 02          | Day 4         | MA          | 36.6        | None         | None    | None    | None       | None     | None   |
| CV01EM012  | 100 µg (18-55 years) | 02          | Day 5         | MA          | 36.3        | None         | None    | None    | None       | None     | None   |
| CV01EM012  | 100 µg (18-55 years) | 02          | Day 6         | MA          | 37.1        | None         | None    | None    | None       | None     | None   |
| CV01EM012  | 100 µg (18-55 years) | 02          | Day 7         | MA          | 36.8        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|------------|-------------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|--------|
| CV01EM012  | 100 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.5       | None         | None     | None    | None       | None     | None   |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | Mild       | None     | None   |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | Mild     | None    | None       | None     | None   |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | 37.3       | None         | Moderate | Mild    | None       | None     | None   |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | 37.3       | None         | Mild     | Mild    | None       | None     | None   |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | 37.1       | None         | Mild     | Mild    | Mild       | Mild     | None   |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | 37.3       | None         | Mild     | None    | Mild       | Mild     | None   |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | 37.3       | None         | Mild     | None    | Mild       | Moderate | None   |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | 37.3       | None         | None     | None    | Mild       | None     | None   |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | 37.4       | None         | None     | None    | None       | None     | None   |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | 37.4       | None         | None     | None    | Mild       | None     | None   |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Day 9         | MA          | N/A        |              |          |         | Mild       |          |        |
| CV01EM016  | 250 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01EM016  | 250 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|------------|--------------|----------|----------|------------|----------|--------|
| CV01EM016  | 250 µg (18-55 years) | 02          | Day 1         | MA          | 37.3       | None         | None     | Mild     | None       | None     | None   |
| CV01EM016  | 250 µg (18-55 years) | 02          | Day 2         | MA          | 37.7       | Mild         | Moderate | Moderate | None       | Mild     | None   |
| CV01EM016  | 250 µg (18-55 years) | 02          | Day 3         | MA          | 37.3       | None         | Mild     | Mild     | Mild       | None     | None   |
| CV01EM016  | 250 µg (18-55 years) | 02          | Day 4         | MA          | 37.4       | None         | None     | Mild     | None       | None     | None   |
| CV01EM016  | 250 µg (18-55 years) | 02          | Day 5         | MA          | 37.5       | None         | Moderate | None     | None       | None     | None   |
| CV01EM016  | 250 µg (18-55 years) | 02          | Day 6         | MA          | 37.5       | None         | Mild     | None     | None       | None     | None   |
| CV01EM016  | 250 µg (18-55 years) | 02          | Day 7         | MA          | 37.4       | None         | None     | None     | None       | None     | None   |
| CV01EM016  | 250 µg (18-55 years) | 02          | Day 8         | MA          | 37.1       | None         | None     | None     | None       | None     | None   |
| CV01EM020  | 250 µg (18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01EM020  | 250 µg (18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01EM020  | 250 µg (18-55 years) | 01          | Day 1         | MA          | 36.6       | None         | None     | None     | None       | None     | Mild   |
| CV01EM020  | 250 µg (18-55 years) | 01          | Day 2         | MA          | 36.4       | None         | Mild     | None     | None       | None     | Mild   |
| CV01EM020  | 250 µg (18-55 years) | 01          | Day 3         | MA          | 36.5       | None         | Mild     | Mild     | None       | None     | None   |
| CV01EM020  | 250 µg (18-55 years) | 01          | Day 4         | MA          | 36.6       | None         | Mild     | None     | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C)  | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea   |
|------------|----------------------|-------------|---------------|-------------|-------------|--------------|----------|----------|------------|----------|----------|
| CV01EM020  | 250 µg (18-55 years) | 01          | Day 5         | MA          | 36.6        | None         | Mild     | None     | None       | None     | None     |
| CV01EM020  | 250 µg (18-55 years) | 01          | Day 6         | MA          | 36.6        | None         | Mild     | None     | None       | None     | None     |
| CV01EM020  | 250 µg (18-55 years) | 01          | Day 7         | MA          | 36.5        | None         | None     | None     | None       | None     | None     |
| CV01EM020  | 250 µg (18-55 years) | 01          | Day 8         | MA          | 36.6        | None         | None     | None     | None       | None     | None     |
| CV01EM020  | 250 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A         | None         | None     | None     | None       | None     | None     |
| CV01EM020  | 250 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A         | None         | None     | None     | None       | None     | None     |
| CV01EM020  | 250 µg (18-55 years) | 02          | Day 1         | MA          | 38.3 (Mild) | Moderate     | Moderate | Moderate | Moderate   | Mild     | Moderate |
| CV01EM020  | 250 µg (18-55 years) | 02          | Day 2         | MA          | 36.7        | Moderate     | Moderate | Moderate | Mild       | Mild     | None     |
| CV01EM020  | 250 µg (18-55 years) | 02          | Day 3         | MA          | 36.9        | None         | Mild     | None     | None       | Mild     | None     |
| CV01EM020  | 250 µg (18-55 years) | 02          | Day 4         | MA          | 36.7        | None         | None     | None     | None       | None     | None     |
| CV01EM020  | 250 µg (18-55 years) | 02          | Day 5         | MA          | 36.7        | None         | None     | None     | None       | None     | None     |
| CV01EM020  | 250 µg (18-55 years) | 02          | Day 6         | MA          | 36.4        | None         | None     | None     | None       | None     | None     |
| CV01EM020  | 250 µg (18-55 years) | 02          | Day 7         | MA          | 36.5        | None         | None     | None     | None       | None     | None     |
| CV01EM020  | 250 µg (18-55 years) | 02          | Day 8         | MA          | 36.5        | None         | None     | None     | None       | None     | None     |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01EM023  | 100 µg (56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM023  | 100 µg (56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM023  | 100 µg (56-70 years) | 01          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM023  | 100 µg (56-70 years) | 01          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM023  | 100 µg (56-70 years) | 01          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM023  | 100 µg (56-70 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM023  | 100 µg (56-70 years) | 01          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM023  | 100 µg (56-70 years) | 01          | Day 6         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01EM023  | 100 µg (56-70 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM023  | 100 µg (56-70 years) | 01          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM023  | 100 µg (56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM023  | 100 µg (56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM023  | 100 µg (56-70 years) | 02          | Day 1         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM023  | 100 µg (56-70 years) | 02          | Day 2         | MA          | 36.7       | None         | None    | Mild    | None       | Mild     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01EM023  | 100 µg<br>(56-70 years) | 02          | Day 3         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01EM023  | 100 µg<br>(56-70 years) | 02          | Day 4         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM023  | 100 µg<br>(56-70 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM023  | 100 µg<br>(56-70 years) | 02          | Day 6         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM023  | 100 µg<br>(56-70 years) | 02          | Day 7         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01EM023  | 100 µg<br>(56-70 years) | 02          | Day 8         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM024  | 100 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM024  | 100 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM024  | 100 µg<br>(56-70 years) | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM024  | 100 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM024  | 100 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM024  | 100 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM024  | 100 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM024  | 100 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|------------|--------------|----------|----------|------------|----------|--------|
| CV01EM024  | 100 µg (56-70 years) | 01          | Day 7         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01EM024  | 100 µg (56-70 years) | 01          | Day 8         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01EM024  | 100 µg (56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01EM024  | 100 µg (56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01EM024  | 100 µg (56-70 years) | 02          | Day 1         | MA          | 36.7       | None         | Mild     | Mild     | None       | None     | None   |
| CV01EM024  | 100 µg (56-70 years) | 02          | Day 2         | MA          | 37.8       | Mild         | Moderate | Moderate | Mild       | None     | None   |
| CV01EM024  | 100 µg (56-70 years) | 02          | Day 3         | MA          | 36.8       | None         | Mild     | Mild     | Mild       | None     | None   |
| CV01EM024  | 100 µg (56-70 years) | 02          | Day 4         | MA          | 37.2       | None         | Mild     | None     | None       | Mild     | None   |
| CV01EM024  | 100 µg (56-70 years) | 02          | Day 5         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01EM024  | 100 µg (56-70 years) | 02          | Day 6         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01EM024  | 100 µg (56-70 years) | 02          | Day 7         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01EM024  | 100 µg (56-70 years) | 02          | Day 8         | MA          | 37         | None         | None     | None     | None       | None     | None   |
| CV01EM025  | 25 µg (56-70 years)  | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01EM025  | 25 µg (56-70 years)  | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01EM025  | 25 µg<br>(56-70 years) | 01          | Day 1         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01EM025  | 25 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM025  | 25 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM025  | 25 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01EM025  | 25 µg<br>(56-70 years) | 01          | Day 5         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01EM025  | 25 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM025  | 25 µg<br>(56-70 years) | 01          | Day 7         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01EM025  | 25 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM025  | 25 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM025  | 25 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM025  | 25 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01EM025  | 25 µg<br>(56-70 years) | 02          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM025  | 25 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM025  | 25 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01EM025  | 25 µg<br>(56-70 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM025  | 25 µg<br>(56-70 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM025  | 25 µg<br>(56-70 years) | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM025  | 25 µg<br>(56-70 years) | 02          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Day 1         | MA          | 37.2       | None         | None    | None    | None       | Mild     | None   |
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Day 2         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Day 3         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Day 4         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Day 5         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Day 6         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Day 7         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Day 8         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group   | Dose Number | Post Dose Day | Assessment* | Fever (°C)    | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea |
|------------|---------------------|-------------|---------------|-------------|---------------|--------------|----------|----------|------------|----------|--------|
| CV01EM027  | 25 µg (56-70 years) | 02          | Pre-Dose      | Clinic      | N/A           | None         | None     | None     | None       | None     | None   |
| CV01EM027  | 25 µg (56-70 years) | 02          | Post-Dose     | Clinic      | N/A           | None         | None     | None     | None       | None     | None   |
| CV01EM027  | 25 µg (56-70 years) | 02          | Day 1         | MA          | 37.1          | None         | None     | None     | None       | None     | None   |
| CV01EM027  | 25 µg (56-70 years) | 02          | Day 2         | MA          | 39.2 (Severe) | Moderate     | Moderate | Moderate | Moderate   | Moderate | Mild   |
| CV01EM027  | 25 µg (56-70 years) | 02          | Day 3         | MA          | 38.2 (Mild)   | None         | None     | None     | None       | Mild     | None   |
| CV01EM027  | 25 µg (56-70 years) | 02          | Day 4         | MA          | 37.1          | None         | None     | None     | None       | None     | None   |
| CV01EM027  | 25 µg (56-70 years) | 02          | Day 5         | MA          | 37            | None         | None     | None     | None       | None     | None   |
| CV01EM027  | 25 µg (56-70 years) | 02          | Day 6         | MA          | 37.1          | None         | None     | None     | None       | None     | None   |
| CV01EM027  | 25 µg (56-70 years) | 02          | Day 7         | MA          | 37.1          | None         | None     | None     | None       | None     | None   |
| CV01EM027  | 25 µg (56-70 years) | 02          | Day 8         | MA          | 37            | None         | None     | None     | None       | None     | None   |
| CV01EM029  | 25 µg (56-70 years) | 01          | Pre-Dose      | Clinic      | N/A           | None         | None     | None     | None       | None     | None   |
| CV01EM029  | 25 µg (56-70 years) | 01          | Post-Dose     | Clinic      | N/A           | None         | None     | None     | None       | None     | None   |
| CV01EM029  | 25 µg (56-70 years) | 01          | Day 1         | MA          | 36.7          | None         | None     | None     | None       | None     | None   |
| CV01EM029  | 25 µg (56-70 years) | 01          | Day 2         | MA          | 36.7          | None         | None     | None     | Moderate   | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01EM029  | 25 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM029  | 25 µg<br>(56-70 years) | 01          | Day 4         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01EM029  | 25 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01EM029  | 25 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01EM029  | 25 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01EM029  | 25 µg<br>(56-70 years) | 01          | Day 8         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Day 1         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Day 2         | MA          | 36.9       | None         | None    | None    | None       | Mild     | None   |
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Day 5         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Day 7         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Day 8         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Day 1         | MA          | 36.7       | None         | Mild    | None    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.8       | None         | Mild    | Mild    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01EM030  | 25 µg<br>(56-70 years)  | 02          | Day 1         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years)  | 02          | Day 2         | MA          | 37.3       | None         | Mild    | Mild    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years)  | 02          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years)  | 02          | Day 4         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years)  | 02          | Day 5         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years)  | 02          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years)  | 02          | Day 7         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01EM030  | 25 µg<br>(56-70 years)  | 02          | Day 8         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01EM032  | 100 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM032  | 100 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM032  | 100 µg<br>(56-70 years) | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM032  | 100 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM032  | 100 µg<br>(56-70 years) | 01          | Day 3         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01EM032  | 100 µg<br>(56-70 years) | 01          | Day 4         | MA          | 37.4       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea   |
|------------|----------------------|-------------|---------------|-------------|------------|--------------|----------|----------|------------|----------|----------|
| CV01EM032  | 100 µg (56-70 years) | 01          | Day 5         | MA          | 37.3       | None         | None     | None     | None       | None     | None     |
| CV01EM032  | 100 µg (56-70 years) | 01          | Day 6         | MA          | 36.7       | None         | None     | None     | None       | None     | None     |
| CV01EM032  | 100 µg (56-70 years) | 01          | Day 7         | MA          | 36.9       | None         | None     | None     | None       | None     | None     |
| CV01EM032  | 100 µg (56-70 years) | 01          | Day 8         | MA          | 37.1       | None         | None     | None     | None       | None     | None     |
| CV01EM032  | 100 µg (56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None     |
| CV01EM032  | 100 µg (56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | None       | None     | None     |
| CV01EM032  | 100 µg (56-70 years) | 02          | Day 1         | MA          | 37.3       | Moderate     | Mild     | Moderate | Moderate   | Moderate | Moderate |
| CV01EM032  | 100 µg (56-70 years) | 02          | Day 2         | MA          | 37.4       | Moderate     | Moderate | Moderate | Moderate   | Moderate | Moderate |
| CV01EM032  | 100 µg (56-70 years) | 02          | Day 3         | MA          | 36.7       | None         | Mild     | None     | None       | None     | None     |
| CV01EM032  | 100 µg (56-70 years) | 02          | Day 4         | MA          | 37.3       | None         | None     | None     | None       | None     | None     |
| CV01EM032  | 100 µg (56-70 years) | 02          | Day 5         | MA          | 36.9       | None         | None     | None     | None       | None     | None     |
| CV01EM032  | 100 µg (56-70 years) | 02          | Day 6         | MA          | 36.9       | None         | None     | None     | None       | None     | None     |
| CV01EM032  | 100 µg (56-70 years) | 02          | Day 7         | MA          | 37.2       | None         | None     | None     | None       | None     | None     |
| CV01EM032  | 100 µg (56-70 years) | 02          | Day 8         | MA          | 36.9       | None         | None     | None     | None       | None     | None     |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C)  | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|-------------|--------------|---------|---------|------------|----------|--------|
| CV01EM033  | 100 µg (56-70 years) | 01          | Pre-Dose      | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01EM033  | 100 µg (56-70 years) | 01          | Post-Dose     | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01EM033  | 100 µg (56-70 years) | 01          | Day 1         | MA          | 36.9        | None         | Mild    | None    | None       | None     | None   |
| CV01EM033  | 100 µg (56-70 years) | 01          | Day 2         | MA          | 36.7        | None         | None    | Mild    | None       | None     | None   |
| CV01EM033  | 100 µg (56-70 years) | 01          | Day 3         | MA          | 36.8        | None         | None    | None    | None       | None     | None   |
| CV01EM033  | 100 µg (56-70 years) | 01          | Day 4         | MA          | 36.7        | None         | None    | None    | None       | None     | None   |
| CV01EM033  | 100 µg (56-70 years) | 01          | Day 5         | MA          | 36.9        | None         | None    | None    | None       | None     | None   |
| CV01EM033  | 100 µg (56-70 years) | 01          | Day 6         | MA          | 36.7        | None         | None    | None    | None       | None     | None   |
| CV01EM033  | 100 µg (56-70 years) | 01          | Day 7         | MA          | 36.9        | None         | None    | None    | None       | None     | None   |
| CV01EM033  | 100 µg (56-70 years) | 01          | Day 8         | MA          | 36.8        | None         | None    | None    | None       | None     | None   |
| CV01EM033  | 100 µg (56-70 years) | 02          | Pre-Dose      | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01EM033  | 100 µg (56-70 years) | 02          | Post-Dose     | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01EM033  | 100 µg (56-70 years) | 02          | Day 1         | MA          | 36.9        | None         | None    | None    | None       | None     | None   |
| CV01EM033  | 100 µg (56-70 years) | 02          | Day 2         | MA          | 38.4 (Mild) | Mild         | Mild    | Mild    | None       | Mild     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01EM033  | 100 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM033  | 100 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM033  | 100 µg<br>(56-70 years) | 02          | Day 5         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01EM033  | 100 µg<br>(56-70 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM033  | 100 µg<br>(56-70 years) | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM033  | 100 µg<br>(56-70 years) | 02          | Day 8         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01EM039  | 100 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM039  | 100 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM039  | 100 µg<br>(56-70 years) | 01          | Day 1         | MA          | 37.1       | None         | Mild    | None    | None       | None     | None   |
| CV01EM039  | 100 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM039  | 100 µg<br>(56-70 years) | 01          | Day 3         | MA          | 37         | None         | Mild    | None    | None       | None     | None   |
| CV01EM039  | 100 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM039  | 100 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM039  | 100 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01EM039  | 100 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM039  | 100 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM039  | 100 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM039  | 100 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM039  | 100 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.7       | None         | Mild    | None    | None       | Mild     | None   |
| CV01EM039  | 100 µg<br>(56-70 years) | 02          | Day 2         | MA          | 37.2       | None         | Mild    | None    | None       | Mild     | None   |
| CV01EM039  | 100 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.9       | None         | Mild    | None    | None       | None     | None   |
| CV01EM039  | 100 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01EM039  | 100 µg<br>(56-70 years) | 02          | Day 5         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01EM039  | 100 µg<br>(56-70 years) | 02          | Day 6         | MA          | 36.7       | Mild         | None    | None    | None       | None     | Mild   |
| CV01EM039  | 100 µg<br>(56-70 years) | 02          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM039  | 100 µg<br>(56-70 years) | 02          | Day 8         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM041  | 25 µg<br>(56-70 years)  | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM041  | 25 µg<br>(56-70 years)  | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|--------|
| CV01EM041  | 25 µg<br>(56-70 years) | 01          | Day 1         | MA          | 36.6       | None         | None     | None    | None       | None     | None   |
| CV01EM041  | 25 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01EM041  | 25 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01EM041  | 25 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.9       | None         | None     | None    | None       | None     | None   |
| CV01EM041  | 25 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01EM041  | 25 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.8       | None         | None     | None    | None       | None     | None   |
| CV01EM041  | 25 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01EM041  | 25 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.8       | None         | None     | None    | None       | None     | None   |
| CV01EM041  | 25 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01EM041  | 25 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01EM041  | 25 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.8       | None         | None     | None    | None       | None     | None   |
| CV01EM041  | 25 µg<br>(56-70 years) | 02          | Day 2         | MA          | 36.9       | None         | Moderate | Mild    | None       | None     | None   |
| CV01EM041  | 25 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01EM041  | 25 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|------------|-------------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|--------|
| CV01EM041  | 25 µg<br>(56-70 years)  | 02          | Day 5         | MA          | 36.9       | Mild         | Moderate | None    | None       | None     | None   |
| CV01EM041  | 25 µg<br>(56-70 years)  | 02          | Day 6         | MA          | 36.8       | None         | Mild     | None    | None       | None     | None   |
| CV01EM041  | 25 µg<br>(56-70 years)  | 02          | Day 7         | MA          | 37         | None         | Mild     | None    | None       | None     | None   |
| CV01EM041  | 25 µg<br>(56-70 years)  | 02          | Day 8         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Day 1         | MA          | 37.2       | None         | None     | None    | None       | None     | None   |
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Day 2         | MA          | 37         | None         | None     | None    | None       | None     | None   |
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Day 3         | MA          | 37.1       | None         | None     | None    | None       | None     | None   |
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Day 4         | MA          | 37         | None         | None     | None    | None       | None     | None   |
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Day 5         | MA          | 37.1       | None         | None     | None    | None       | None     | None   |
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Day 6         | MA          | 37.1       | None         | None     | None    | None       | None     | None   |
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Day 7         | MA          | 37         | None         | None     | None    | None       | None     | None   |
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Day 8         | MA          | 37.1       | None         | None     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group   | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|---------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01EM049  | 50 µg (18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM049  | 50 µg (18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM049  | 50 µg (18-55 years) | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM049  | 50 µg (18-55 years) | 01          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM049  | 50 µg (18-55 years) | 01          | Day 3         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01EM049  | 50 µg (18-55 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM049  | 50 µg (18-55 years) | 01          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM049  | 50 µg (18-55 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM049  | 50 µg (18-55 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM049  | 50 µg (18-55 years) | 01          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM049  | 50 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM049  | 50 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM049  | 50 µg (18-55 years) | 02          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | Mild     | None   |
| CV01EM049  | 50 µg (18-55 years) | 02          | Day 2         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea   |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|----------|
| CV01EM049  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.7       | None         | None     | None    | None       | None     | None     |
| CV01EM049  | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.8       | None         | None     | None    | None       | None     | None     |
| CV01EM049  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.6       | None         | None     | None    | None       | None     | None     |
| CV01EM049  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.7       | None         | None     | None    | None       | None     | None     |
| CV01EM049  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.9       | None         | None     | None    | None       | None     | None     |
| CV01EM049  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.8       | None         | None     | None    | None       | None     | None     |
| CV01EM051  | 50 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | Mild       | None     | None     |
| CV01EM051  | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | Mild       | None     | None     |
| CV01EM051  | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | 37.3       | None         | Mild     | None    | None       | None     | Moderate |
| CV01EM051  | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.8       | None         | Mild     | None    | None       | None     | None     |
| CV01EM051  | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | 37.2       | None         | Moderate | None    | None       | None     | Moderate |
| CV01EM051  | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.8       | None         | Moderate | None    | None       | None     | None     |
| CV01EM051  | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.7       | None         | Mild     | None    | None       | None     | None     |
| CV01EM051  | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.9       | None         | Mild     | None    | None       | None     | None     |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group   | Dose Number | Post Dose Day | Assessment* | Fever (°C)  | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|------------|---------------------|-------------|---------------|-------------|-------------|--------------|----------|---------|------------|----------|--------|
| CV01EM051  | 50 µg (18-55 years) | 01          | Day 7         | MA          | 36.7        | None         | None     | None    | None       | None     | None   |
| CV01EM051  | 50 µg (18-55 years) | 01          | Day 8         | MA          | 36.7        | None         | None     | None    | None       | None     | None   |
| CV01EM051  | 50 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A         | None         | None     | None    | None       | None     | None   |
| CV01EM051  | 50 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A         | None         | None     | None    | None       | None     | None   |
| CV01EM051  | 50 µg (18-55 years) | 02          | Day 1         | MA          | 37.2        | None         | Moderate | None    | None       | None     | Mild   |
| CV01EM051  | 50 µg (18-55 years) | 02          | Day 2         | MA          | 38.2 (Mild) | None         | Moderate | None    | None       | Severe   | None   |
| CV01EM051  | 50 µg (18-55 years) | 02          | Day 3         | MA          | 36.8        | None         | None     | None    | None       | None     | None   |
| CV01EM051  | 50 µg (18-55 years) | 02          | Day 4         | MA          | 37.1        | None         | None     | None    | None       | None     | None   |
| CV01EM051  | 50 µg (18-55 years) | 02          | Day 5         | MA          | 36.9        | None         | None     | None    | None       | None     | None   |
| CV01EM051  | 50 µg (18-55 years) | 02          | Day 6         | MA          | 36.8        | None         | None     | None    | None       | None     | None   |
| CV01EM051  | 50 µg (18-55 years) | 02          | Day 7         | MA          | 36.9        | None         | None     | None    | None       | None     | None   |
| CV01EM051  | 50 µg (18-55 years) | 02          | Day 8         | MA          | 36.9        | None         | None     | None    | None       | None     | None   |
| CV01EM053  | 50 µg (18-55 years) | 01          | Pre-Dose      | Clinic      | N/A         | None         | None     | None    | None       | None     | None   |
| CV01EM053  | 50 µg (18-55 years) | 01          | Post-Dose     | Clinic      | N/A         | None         | None     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group   | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea |
|------------|---------------------|-------------|---------------|-------------|------------|--------------|----------|----------|------------|----------|--------|
| CV01EM053  | 50 µg (18-55 years) | 01          | Day 1         | MA          | 36.8       | None         | None     | None     | None       | None     | None   |
| CV01EM053  | 50 µg (18-55 years) | 01          | Day 2         | MA          | 37.1       | None         | None     | None     | None       | None     | None   |
| CV01EM053  | 50 µg (18-55 years) | 01          | Day 3         | MA          | 36.9       | None         | None     | None     | None       | None     | None   |
| CV01EM053  | 50 µg (18-55 years) | 01          | Day 4         | MA          | 36.9       | None         | None     | None     | None       | None     | None   |
| CV01EM053  | 50 µg (18-55 years) | 01          | Day 5         | MA          | 37.1       | None         | None     | None     | None       | None     | None   |
| CV01EM053  | 50 µg (18-55 years) | 01          | Day 6         | MA          | 36.8       | None         | None     | None     | None       | None     | None   |
| CV01EM053  | 50 µg (18-55 years) | 01          | Day 7         | MA          | 37.3       | None         | None     | None     | None       | None     | None   |
| CV01EM053  | 50 µg (18-55 years) | 01          | Day 8         | MA          | 37.2       | None         | None     | None     | None       | None     | None   |
| CV01EM053  | 50 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01EM053  | 50 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01EM053  | 50 µg (18-55 years) | 02          | Day 1         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01EM053  | 50 µg (18-55 years) | 02          | Day 2         | MA          | 37.7       | None         | Moderate | Moderate | Moderate   | Moderate | None   |
| CV01EM053  | 50 µg (18-55 years) | 02          | Day 3         | MA          | 37.3       | None         | Moderate | Moderate | Moderate   | Moderate | None   |
| CV01EM053  | 50 µg (18-55 years) | 02          | Day 4         | MA          | 37.1       | None         | Mild     | Mild     | Mild       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01EM053  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01EM053  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01EM053  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01EM053  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01EM054  | 50 µg<br>(18-55 years)  | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years)  | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years)  | 02          | Day 1         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years)  | 02          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years)  | 02          | Day 3         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years)  | 02          | Day 4         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years)  | 02          | Day 5         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years)  | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years)  | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01EM054  | 50 µg<br>(18-55 years)  | 02          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC001  | 100 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC001  | 100 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | Mild    | None    | None       | None     | None   |
| CV01HC001  | 100 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC001  | 100 µg<br>(18-55 years) | 01          | Day 2         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|--------|
| CV01HC001  | 100 µg (18-55 years) | 01          | Day 3         | MA          | 37         | None         | None     | None    | None       | None     | None   |
| CV01HC001  | 100 µg (18-55 years) | 01          | Day 4         | MA          | 36.8       | None         | None     | None    | None       | None     | None   |
| CV01HC001  | 100 µg (18-55 years) | 01          | Day 5         | MA          | 36.8       | None         | None     | None    | None       | None     | None   |
| CV01HC001  | 100 µg (18-55 years) | 01          | Day 6         | MA          | 37.1       | None         | None     | None    | None       | None     | None   |
| CV01HC001  | 100 µg (18-55 years) | 01          | Day 7         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01HC001  | 100 µg (18-55 years) | 01          | Day 8         | MA          | 36.8       | None         | None     | None    | None       | None     | None   |
| CV01HC001  | 100 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01HC001  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01HC001  | 100 µg (18-55 years) | 02          | Day 1         | MA          | 36.9       | None         | None     | Mild    | None       | None     | None   |
| CV01HC001  | 100 µg (18-55 years) | 02          | Day 2         | MA          | 37.4       | None         | Moderate | Mild    | None       | None     | None   |
| CV01HC001  | 100 µg (18-55 years) | 02          | Day 3         | MA          | 36.9       | None         | None     | None    | None       | None     | None   |
| CV01HC001  | 100 µg (18-55 years) | 02          | Day 4         | MA          | 37.4       | None         | None     | None    | None       | None     | None   |
| CV01HC001  | 100 µg (18-55 years) | 02          | Day 5         | MA          | 36.9       | None         | None     | None    | None       | None     | None   |
| CV01HC001  | 100 µg (18-55 years) | 02          | Day 6         | MA          | 36.9       | None         | None     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01HC001  | 100 µg (18-55 years) | 02          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC001  | 100 µg (18-55 years) | 02          | Day 8         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC003  | 100 µg (18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC003  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC003  | 100 µg (18-55 years) | 01          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC003  | 100 µg (18-55 years) | 01          | Day 2         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01HC003  | 100 µg (18-55 years) | 01          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC003  | 100 µg (18-55 years) | 01          | Day 4         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01HC003  | 100 µg (18-55 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC003  | 100 µg (18-55 years) | 01          | Day 6         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01HC003  | 100 µg (18-55 years) | 01          | Day 7         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01HC003  | 100 µg (18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC003  | 100 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC003  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia  | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|----------|------------|----------|--------|
| CV01HC003  | 100 µg (18-55 years) | 02          | Day 1         | MA          | 36.7       | None         | Mild    | Moderate | None       | None     | None   |
| CV01HC003  | 100 µg (18-55 years) | 02          | Day 2         | MA          | 37.6       | Mild         | Mild    | Mild     | None       | Mild     | None   |
| CV01HC003  | 100 µg (18-55 years) | 02          | Day 3         | MA          | 37.1       | None         | None    | Mild     | None       | None     | None   |
| CV01HC003  | 100 µg (18-55 years) | 02          | Day 4         | MA          | 37         | None         | None    | None     | None       | None     | None   |
| CV01HC003  | 100 µg (18-55 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None     | None       | None     | None   |
| CV01HC003  | 100 µg (18-55 years) | 02          | Day 6         | MA          | 37         | None         | None    | None     | None       | None     | None   |
| CV01HC003  | 100 µg (18-55 years) | 02          | Day 7         | MA          | 36.6       | None         | None    | None     | None       | None     | None   |
| CV01HC003  | 100 µg (18-55 years) | 02          | Day 8         | MA          | 36.8       | None         | None    | None     | None       | None     | None   |
| CV01HC004  | 100 µg (18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None     | None       | None     | None   |
| CV01HC004  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None     | None       | None     | None   |
| CV01HC004  | 100 µg (18-55 years) | 01          | Day 1         | MA          | 37.2       | None         | None    | None     | None       | None     | None   |
| CV01HC004  | 100 µg (18-55 years) | 01          | Day 2         | MA          | 37.5       | None         | None    | None     | None       | None     | None   |
| CV01HC004  | 100 µg (18-55 years) | 01          | Day 3         | MA          | 36.5       | None         | None    | None     | None       | Mild     | None   |
| CV01HC004  | 100 µg (18-55 years) | 01          | Day 4         | MA          | 37.1       | None         | None    | None     | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|--------|
| CV01HC004  | 100 µg (18-55 years) | 01          | Day 5         | MA          | 36.9       | None         | None     | None    | None       | None     | None   |
| CV01HC004  | 100 µg (18-55 years) | 01          | Day 6         | MA          | 36.9       | None         | None     | None    | None       | None     | None   |
| CV01HC004  | 100 µg (18-55 years) | 01          | Day 7         | MA          | 37.1       | None         | None     | None    | None       | None     | None   |
| CV01HC004  | 100 µg (18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01HC004  | 100 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01HC004  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01HC004  | 100 µg (18-55 years) | 02          | Day 1         | MA          | 36.7       | None         | Mild     | None    | None       | Mild     | None   |
| CV01HC004  | 100 µg (18-55 years) | 02          | Day 2         | MA          | 37.8       | Mild         | Moderate | None    | None       | Mild     | None   |
| CV01HC004  | 100 µg (18-55 years) | 02          | Day 3         | MA          | 37         | None         | None     | None    | None       | None     | None   |
| CV01HC004  | 100 µg (18-55 years) | 02          | Day 4         | MA          | 37         | None         | None     | None    | None       | None     | None   |
| CV01HC004  | 100 µg (18-55 years) | 02          | Day 5         | MA          | 37.2       | None         | None     | None    | None       | None     | None   |
| CV01HC004  | 100 µg (18-55 years) | 02          | Day 6         | MA          | 36.8       | None         | None     | None    | None       | None     | None   |
| CV01HC004  | 100 µg (18-55 years) | 02          | Day 7         | MA          | 37.1       | None         | None     | None    | None       | None     | None   |
| CV01HC004  | 100 µg (18-55 years) | 02          | Day 8         | MA          | 37.1       | None         | None     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|------------|--------------|----------|----------|------------|----------|--------|
| CV01HC007  | 100 µg (18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01HC007  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | Mild       | None     | None   |
| CV01HC007  | 100 µg (18-55 years) | 01          | Day 1         | MA          | 36.6       | None         | None     | None     | None       | None     | None   |
| CV01HC007  | 100 µg (18-55 years) | 01          | Day 2         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01HC007  | 100 µg (18-55 years) | 01          | Day 3         | MA          | 36.8       | None         | None     | None     | None       | None     | None   |
| CV01HC007  | 100 µg (18-55 years) | 01          | Day 4         | MA          | 36.6       | None         | None     | None     | None       | None     | None   |
| CV01HC007  | 100 µg (18-55 years) | 01          | Day 5         | MA          | 36.6       | None         | None     | None     | None       | None     | None   |
| CV01HC007  | 100 µg (18-55 years) | 01          | Day 6         | MA          | 36.9       | None         | None     | None     | None       | None     | None   |
| CV01HC007  | 100 µg (18-55 years) | 01          | Day 7         | MA          | 36.9       | None         | None     | None     | None       | None     | None   |
| CV01HC007  | 100 µg (18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01HC007  | 100 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01HC007  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01HC007  | 100 µg (18-55 years) | 02          | Day 1         | MA          | 37.7       | Moderate     | Moderate | Moderate | Moderate   | Mild     | Mild   |
| CV01HC007  | 100 µg (18-55 years) | 02          | Day 2         | MA          | 37.2       | Mild         | Mild     | Mild     | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01HC007  | 100 µg (18-55 years) | 02          | Day 3         | MA          | 37.1       | None         | None    | Mild    | None       | None     | None   |
| CV01HC007  | 100 µg (18-55 years) | 02          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC007  | 100 µg (18-55 years) | 02          | Day 5         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01HC007  | 100 µg (18-55 years) | 02          | Day 6         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01HC007  | 100 µg (18-55 years) | 02          | Day 7         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01HC007  | 100 µg (18-55 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | Mild    | None       | None     | None   |
| CV01HC007  | 100 µg (18-55 years) | 02          | Day 12        | MA          | N/A        |              |         | Mild    |            |          |        |
| CV01HC008  | 100 µg (18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC008  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC008  | 100 µg (18-55 years) | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC008  | 100 µg (18-55 years) | 01          | Day 2         | MA          | 37.8       | None         | None    | None    | None       | None     | None   |
| CV01HC008  | 100 µg (18-55 years) | 01          | Day 3         | MA          | 37.7       | None         | None    | None    | None       | None     | None   |
| CV01HC008  | 100 µg (18-55 years) | 01          | Day 4         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01HC008  | 100 µg (18-55 years) | 01          | Day 5         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01HC008  | 100 µg (18-55 years) | 01          | Day 6         | MA          | 37.4       | None         | None    | None    | None       | None     | None   |
| CV01HC008  | 100 µg (18-55 years) | 01          | Day 7         | MA          | 37.4       | None         | None    | None    | None       | None     | None   |
| CV01HC008  | 100 µg (18-55 years) | 01          | Day 8         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01HC008  | 100 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC008  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC008  | 100 µg (18-55 years) | 02          | Day 1         | MA          | 37         | Mild         | None    | None    | None       | None     | None   |
| CV01HC008  | 100 µg (18-55 years) | 02          | Day 2         | MA          | 37.3       | Mild         | Mild    | None    | None       | None     | Mild   |
| CV01HC008  | 100 µg (18-55 years) | 02          | Day 3         | MA          | 36.1       | None         | None    | None    | None       | None     | None   |
| CV01HC008  | 100 µg (18-55 years) | 02          | Day 4         | MA          | 36.1       | None         | None    | None    | None       | None     | None   |
| CV01HC008  | 100 µg (18-55 years) | 02          | Day 5         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01HC008  | 100 µg (18-55 years) | 02          | Day 6         | MA          | 36.1       | None         | None    | None    | None       | None     | None   |
| CV01HC008  | 100 µg (18-55 years) | 02          | Day 7         | MA          | 36         | None         | None    | None    | None       | None     | None   |
| CV01HC008  | 100 µg (18-55 years) | 02          | Day 8         | MA          | 35.8       | None         | None    | None    | None       | None     | None   |
| CV01HC012  | 250 µg (18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|--------|
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.5       | None         | None     | None    | None       | None     | None   |
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.2       | None         | None     | None    | None       | None     | None   |
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.5       | None         | None     | None    | None       | None     | None   |
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.6       | None         | None     | None    | None       | None     | None   |
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.6       | None         | None     | None    | None       | None     | None   |
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.3       | None         | None     | None    | None       | None     | None   |
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.6       | Moderate     | None     | None    | None       | Moderate | None   |
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37.1       | Moderate     | Moderate | Mild    | Mild       | Moderate | None   |
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 02          | Day 3         | MA          | 37.1       | None         | Mild     | None    | None       | Mild     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>2 | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 02          | Day 2         | MA          | 36.7       | None         | Mild    | None    | None       | Mild     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>3 | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia  | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|----------|------------|----------|--------|
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.9       | None         | None    | None     | None       | Mild     | None   |
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None     | None       | Mild     | None   |
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.8       | None         | None    | None     | None       | None     | None   |
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | 37.1       | None         | None    | None     | None       | None     | None   |
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.8       | None         | None    | None     | None       | None     | None   |
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None     | None       | Mild     | None   |
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.9       | None         | None    | None     | None       | None     | None   |
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None     | None       | None     | None   |
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None     | None       | None     | None   |
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.7       | Mild         | None    | Moderate | None       | None     | None   |
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37.3       | Mild         | None    | Mild     | None       | None     | None   |
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 02          | Day 3         | MA          | 37.1       | None         | None    | None     | None       | Mild     | None   |
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.8       | None         | None    | None     | None       | None     | None   |
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.9       | None         | None    | None     | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | Mild     | None   |
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | Mild     | None   |
| CV01HC01<br>6 | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years)  | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | Mild     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years)  | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | Mild     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years)  | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | Mild     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years)  | 01          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years)  | 01          | Day 3         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years)  | 01          | Day 4         | MA          | 36.6       | None         | None    | None    | Mild       | Mild     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years)  | 01          | Day 5         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years)  | 01          | Day 6         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years)  | 01          | Day 7         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years)  | 01          | Day 8         | MA          | 36.4       | None         | None    | None    | Moderate   | None     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years)  | 01          | Day 10        | MA          | N/A        |              |         |         | Mild       |          |        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01HC02<br>6 | 25 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years) | 02          | Day 2         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years) | 02          | Day 6         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years) | 02          | Day 7         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>6 | 25 µg<br>(56-70 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>7 | 25 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>7 | 25 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>7 | 25 µg<br>(56-70 years) | 01          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>7 | 25 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01HC02<br>7 | 25 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>7 | 25 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>7 | 25 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>7 | 25 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>7 | 25 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.1       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>7 | 25 µg<br>(56-70 years) | 01          | Day 8         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>7 | 25 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>7 | 25 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>7 | 25 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.7       | None         | None    | Mild    | None       | None     | None   |
| CV01HC02<br>7 | 25 µg<br>(56-70 years) | 02          | Day 2         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>7 | 25 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>7 | 25 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>7 | 25 µg<br>(56-70 years) | 02          | Day 5         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>7 | 25 µg<br>(56-70 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01HC02<br>7 | 25 µg<br>(56-70 years)  | 02          | Day 7         | MA          | 36.1       | None         | None    | None    | None       | None     | None   |
| CV01HC02<br>7 | 25 µg<br>(56-70 years)  | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 01          | Day 1         | MA          | 35.7       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.1       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.1       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.1       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 02          | Day 2         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 02          | Day 3         | MA          | 35.8       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36         | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 02          | Day 5         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 02          | Day 6         | MA          | 35.7       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 02          | Day 7         | MA          | 35.9       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>1 | 100 µg<br>(56-70 years) | 02          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years)  | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years)  | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years)  | 01          | Day 1         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years)  | 01          | Day 2         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years)  | 01          | Day 3         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years)  | 01          | Day 4         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01HC03<br>2 | 25 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.7       | None         | Mild    | Mild    | Mild       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.4       | None         | None    | Mild    | Mild       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years) | 02          | Day 2         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years) | 02          | Day 5         | MA          | 36.7       | None         | Mild    | Mild    | None       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years) | 02          | Day 6         | MA          | 36.4       | None         | Mild    | Mild    | None       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years) | 02          | Day 7         | MA          | 36.8       | None         | Mild    | Mild    | None       | None     | None   |
| CV01HC03<br>2 | 25 µg<br>(56-70 years) | 02          | Day 8         | MA          | 36.3       | None         | None    | Mild    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01HC03<br>3 | 25 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>3 | 25 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>3 | 25 µg<br>(56-70 years) | 01          | Day 1         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>3 | 25 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>3 | 25 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>3 | 25 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>3 | 25 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>3 | 25 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>3 | 25 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>3 | 25 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>3 | 25 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>3 | 25 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>3 | 25 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>3 | 25 µg<br>(56-70 years) | 02          | Day 2         | MA          | 36         | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01HC03<br>3 | 25 µg<br>(56-70 years)  | 02          | Day 3         | MA          | 36.1       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>3 | 25 µg<br>(56-70 years)  | 02          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>3 | 25 µg<br>(56-70 years)  | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>3 | 25 µg<br>(56-70 years)  | 02          | Day 6         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>3 | 25 µg<br>(56-70 years)  | 02          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>3 | 25 µg<br>(56-70 years)  | 02          | Day 8         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 01          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.1       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea   |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|----------|----------|------------|----------|----------|
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.2       | None         | None     | None     | None       | None     | None     |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 01          | Day 8         | MA          | 37         | None         | None     | None     | None       | None     | None     |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None     |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | None       | None     | None     |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.2       | None         | None     | None     | None       | None     | None     |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 02          | Day 2         | MA          | 37.8       | Moderate     | Moderate | Moderate | None       | None     | Moderate |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.8       | None         | None     | None     | None       | None     | None     |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36.9       | None         | None     | None     | None       | None     | None     |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 02          | Day 5         | MA          | 36.9       | None         | None     | None     | None       | None     | None     |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 02          | Day 6         | MA          | 36.6       | None         | None     | None     | None       | None     | None     |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 02          | Day 7         | MA          | 36.8       | None         | None     | None     | None       | None     | None     |
| CV01HC03<br>4 | 100 µg<br>(56-70 years) | 02          | Day 8         | MA          | 36.8       | None         | None     | None     | None       | None     | None     |
| CV01HC03<br>5 | 25 µg<br>(56-70 years)  | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None     |
| CV01HC03<br>5 | 25 µg<br>(56-70 years)  | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | None       | None     | None     |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01HC03<br>5 | 25 µg<br>(56-70 years) | 01          | Day 1         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>5 | 25 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>5 | 25 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>5 | 25 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>5 | 25 µg<br>(56-70 years) | 01          | Day 5         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>5 | 25 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>5 | 25 µg<br>(56-70 years) | 01          | Day 7         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>5 | 25 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>5 | 25 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>5 | 25 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>5 | 25 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>5 | 25 µg<br>(56-70 years) | 02          | Day 2         | MA          | 36.8       | None         | None    | Mild    | None       | Mild     | Mild   |
| CV01HC03<br>5 | 25 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>5 | 25 µg<br>(56-70 years) | 02          | Day 4         | MA          | 37         | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01HC03<br>5 | 25 µg<br>(56-70 years)  | 02          | Day 5         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>5 | 25 µg<br>(56-70 years)  | 02          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>5 | 25 µg<br>(56-70 years)  | 02          | Day 7         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>5 | 25 µg<br>(56-70 years)  | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 01          | Day 1         | MA          | 36.2       | None         | Mild    | None    | None       | None     | None   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.2       | None         | Mild    | None    | None       | None     | None   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.7       | None         | Mild    | None    | None       | None     | None   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.1       | None         | None    | None    | None       | None     | None   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|--------|
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 02          | Day 1         | MA          | 37         | None         | Moderate | Mild    | None       | Mild     | Mild   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 02          | Day 2         | MA          | 36.1       | None         | None     | Mild    | None       | Mild     | None   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.2       | None         | None     | None    | None       | None     | None   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36.4       | None         | None     | None    | None       | None     | None   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 02          | Day 5         | MA          | 36.4       | None         | None     | None    | None       | None     | None   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 02          | Day 6         | MA          | 36.4       | None         | None     | None    | None       | None     | None   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 02          | Day 7         | MA          | 36.6       | None         | None     | None    | None       | None     | None   |
| CV01HC03<br>7 | 100 µg<br>(56-70 years) | 02          | Day 8         | MA          | 36.4       | None         | None     | None    | None       | None     | None   |
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 01          | Day 1         | MA          | 36.3       | None         | None     | None    | None       | None     | None   |
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 01          | Day 2         | MA          | 35.7       | None         | None     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|----------|----------|------------|----------|--------|
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 01          | Day 3         | MA          | 35.5       | None         | None     | None     | None       | None     | None   |
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 01          | Day 4         | MA          | N/A        | None         | None     | None     | None       | None     | None   |
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 01          | Day 5         | MA          | 37.1       | None         | None     | None     | None       | None     | None   |
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 01          | Day 6         | MA          | N/A        | None         | None     | None     | None       | None     | None   |
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 01          | Day 7         | MA          | 35.4       | None         | None     | None     | None       | None     | None   |
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 01          | Day 8         | MA          | 35.3       | None         | None     | None     | None       | None     | None   |
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 02          | Day 1         | MA          | 35.2       | None         | None     | None     | None       | None     | None   |
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 02          | Day 2         | MA          | 37.3       | None         | Moderate | Moderate | None       | Mild     | None   |
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 02          | Day 3         | MA          | 35.6       | None         | Mild     | None     | None       | None     | None   |
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 02          | Day 4         | MA          | 35.8       | None         | None     | None     | None       | None     | None   |
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 02          | Day 5         | MA          | 35.6       | None         | None     | None     | None       | None     | None   |
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 02          | Day 6         | MA          | 35.9       | None         | None     | None     | None       | Mild     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|--------|
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 02          | Day 7         | MA          | 35.5       | None         | None     | None    | None       | None     | None   |
| CV01HC03<br>8 | 100 µg<br>(56-70 years) | 02          | Day 8         | MA          | 35.8       | None         | None     | None    | None       | None     | None   |
| CV01HC04<br>8 | 50 µg<br>(18-55 years)  | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01HC04<br>8 | 50 µg<br>(18-55 years)  | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01HC04<br>8 | 50 µg<br>(18-55 years)  | 01          | Day 1         | MA          | 37.7       | None         | None     | None    | None       | None     | None   |
| CV01HC04<br>8 | 50 µg<br>(18-55 years)  | 01          | Day 2         | MA          | 37         | None         | Moderate | None    | None       | None     | None   |
| CV01HC04<br>8 | 50 µg<br>(18-55 years)  | 01          | Day 3         | MA          | 37.1       | None         | None     | None    | None       | Mild     | None   |
| CV01HC04<br>8 | 50 µg<br>(18-55 years)  | 01          | Day 4         | MA          | 37.4       | None         | Mild     | None    | None       | None     | None   |
| CV01HC04<br>8 | 50 µg<br>(18-55 years)  | 01          | Day 5         | MA          | 36.9       | None         | Mild     | Mild    | Mild       | None     | None   |
| CV01HC04<br>8 | 50 µg<br>(18-55 years)  | 01          | Day 6         | MA          | 37.5       | None         | None     | None    | None       | None     | None   |
| CV01HC04<br>8 | 50 µg<br>(18-55 years)  | 01          | Day 7         | MA          | 36.4       | None         | None     | None    | None       | None     | None   |
| CV01HC04<br>8 | 50 µg<br>(18-55 years)  | 01          | Day 8         | MA          | 36.9       | None         | None     | None    | None       | None     | None   |
| CV01HC04<br>8 | 50 µg<br>(18-55 years)  | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01HC04<br>8 | 50 µg<br>(18-55 years)  | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|----------|----------|------------|----------|--------|
| CV01HC048  | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.7       | None         | Mild     | Mild     | None       | None     | None   |
| CV01HC048  | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37.6       | Mild         | Moderate | Moderate | Mild       | Mild     | Mild   |
| CV01HC048  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | 37.1       | None         | Mild     | Mild     | None       | Mild     | None   |
| CV01HC048  | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.9       | None         | None     | None     | None       | None     | None   |
| CV01HC048  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.8       | None         | None     | None     | None       | None     | None   |
| CV01HC048  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.9       | None         | None     | None     | None       | None     | None   |
| CV01HC048  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | 37         | None         | None     | None     | None       | None     | None   |
| CV01HC048  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | 37.1       | None         | None     | None     | None       | None     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.9       | None         | None     | None     | None       | Mild     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.3       | None         | None     | None     | None       | None     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | 37.1       | None         | None     | None     | None       | None     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | 37.1       | None         | None     | None     | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37.7       | None         | None    | None    | None       | Mild     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|--------|
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | Mild     | None    | None       | None     | None   |
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | 37         | None         | Mild     | None    | None       | None     | None   |
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | 37.8       | None         | Mild     | None    | None       | None     | None   |
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | 37.6       | None         | Mild     | None    | None       | None     | None   |
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | 37.2       | None         | None     | None    | None       | None     | None   |
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | 37.2       | None         | None     | None    | None       | None     | None   |
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.6       | None         | None     | None    | None       | None     | None   |
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.1       | None         | None     | None    | None       | None     | None   |
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.1       | None         | None     | None    | None       | None     | None   |
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | 37.6       | Mild         | Moderate | None    | None       | Mild     | None   |
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37.1       | None         | Mild     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC05<br>1 | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC05<br>4 | 50 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC05<br>4 | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | Mild    | None    | None       | None     | None   |
| CV01HC05<br>4 | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC05<br>4 | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.7       | None         | Mild    | None    | None       | None     | None   |
| CV01HC05<br>4 | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01HC05<br>4 | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01HC05<br>4 | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01HC05<br>4 | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.1       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01HC054  | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01HC054  | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.6       | None         | Mild    | None    | None       | None     | None   |
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | 37.3       | None         | None    | None    | None       | Mild     | None   |
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | 37.1       | None         | None    | None    | None       | Mild     | None   |
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group   | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|---------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP005  | 25 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP005  | 25 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP005  | 25 µg (18-55 years) | 02          | Day 1         | MA          | 37.4       | None         | None    | None    | None       | None     | None   |
| CV01KP005  | 25 µg (18-55 years) | 02          | Day 2         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP005  | 25 µg (18-55 years) | 02          | Day 3         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP005  | 25 µg (18-55 years) | 02          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP005  | 25 µg (18-55 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP005  | 25 µg (18-55 years) | 02          | Day 6         | MA          | 37.4       | None         | None    | None    | None       | None     | None   |
| CV01KP005  | 25 µg (18-55 years) | 02          | Day 7         | MA          | 37.1       | None         | None    | None    | None       | Mild     | None   |
| CV01KP005  | 25 µg (18-55 years) | 02          | Day 8         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP006  | 25 µg (18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP006  | 25 µg (18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP006  | 25 µg (18-55 years) | 01          | Day 1         | MA          | 36.7       | None         | Mild    | Mild    | None       | None     | None   |
| CV01KP006  | 25 µg (18-55 years) | 01          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP006  | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP006  | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP006  | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP006  | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP006  | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP006  | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.7       | None         | Mild    | None    | None       | None     | None   |
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | 36.7       | None         | Mild    | None    | None       | None     | None   |
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|--------|
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.9       | None         | None     | None    | None       | None     | None   |
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | 37.5       | None         | Moderate | None    | None       | Mild     | None   |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | 37.1       | None         | None     | None    | None       | None     | None   |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | 37.1       | None         | None     | None    | None       | Mild     | None   |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.8       | None         | None     | None    | None       | None     | None   |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.8       | None         | None     | None    | None       | None     | None   |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | 37.1       | None         | None     | None    | None       | None     | None   |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.9       | None         | None     | None    | None       | None     | None   |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.9       | None         | None     | None    | None       | None     | None   |
| CV01KP007  | 25 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01KP007  | 25 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP007  | 25 µg<br>(18-55 years)  | 02          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | Mild     | None   |
| CV01KP007  | 25 µg<br>(18-55 years)  | 02          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP007  | 25 µg<br>(18-55 years)  | 02          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP007  | 25 µg<br>(18-55 years)  | 02          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP007  | 25 µg<br>(18-55 years)  | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP007  | 25 µg<br>(18-55 years)  | 02          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP007  | 25 µg<br>(18-55 years)  | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP007  | 25 µg<br>(18-55 years)  | 02          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP008  | 100 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP008  | 100 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP008  | 100 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.7       | None         | Mild    | None    | None       | None     | None   |
| CV01KP008  | 100 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP008  | 100 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP008  | 100 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia  | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|----------|------------|----------|--------|
| CV01KP008  | 100 µg (18-55 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None     | None       | None     | None   |
| CV01KP008  | 100 µg (18-55 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None     | None       | None     | None   |
| CV01KP008  | 100 µg (18-55 years) | 01          | Day 7         | MA          | 36.8       | None         | None    | None     | None       | None     | None   |
| CV01KP008  | 100 µg (18-55 years) | 01          | Day 8         | MA          | 36.6       | None         | None    | None     | None       | None     | None   |
| CV01KP008  | 100 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None     | None       | None     | None   |
| CV01KP008  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None     | None       | None     | None   |
| CV01KP008  | 100 µg (18-55 years) | 02          | Day 1         | MA          | 37.7       | Moderate     | Mild    | Moderate | None       | Mild     | Mild   |
| CV01KP008  | 100 µg (18-55 years) | 02          | Day 2         | MA          | 37.2       | None         | Mild    | Mild     | None       | Mild     | Mild   |
| CV01KP008  | 100 µg (18-55 years) | 02          | Day 3         | MA          | 36.7       | None         | None    | None     | None       | Moderate | None   |
| CV01KP008  | 100 µg (18-55 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None     | None       | Mild     | None   |
| CV01KP008  | 100 µg (18-55 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None     | None       | None     | None   |
| CV01KP008  | 100 µg (18-55 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None     | None       | None     | None   |
| CV01KP008  | 100 µg (18-55 years) | 02          | Day 7         | MA          | 36.7       | None         | None    | None     | None       | None     | None   |
| CV01KP008  | 100 µg (18-55 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None     | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C)  | Feverishness | Fatigue | Myalgia  | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|-------------|--------------|---------|----------|------------|----------|--------|
| CV01KP009  | 100 µg (18-55 years) | 01          | Pre-Dose      | Clinic      | N/A         | None         | None    | None     | None       | None     | None   |
| CV01KP009  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | N/A         | None         | None    | None     | None       | None     | None   |
| CV01KP009  | 100 µg (18-55 years) | 01          | Day 1         | MA          | 37.1        | None         | None    | None     | None       | None     | None   |
| CV01KP009  | 100 µg (18-55 years) | 01          | Day 2         | MA          | 37.3        | None         | None    | None     | None       | None     | None   |
| CV01KP009  | 100 µg (18-55 years) | 01          | Day 3         | MA          | 37.2        | None         | None    | None     | None       | Mild     | None   |
| CV01KP009  | 100 µg (18-55 years) | 01          | Day 4         | MA          | 37          | None         | None    | None     | None       | None     | None   |
| CV01KP009  | 100 µg (18-55 years) | 01          | Day 5         | MA          | 37.2        | None         | None    | None     | None       | None     | None   |
| CV01KP009  | 100 µg (18-55 years) | 01          | Day 6         | MA          | 37.6        | None         | None    | None     | None       | None     | None   |
| CV01KP009  | 100 µg (18-55 years) | 01          | Day 7         | MA          | 36.7        | None         | None    | None     | None       | None     | None   |
| CV01KP009  | 100 µg (18-55 years) | 01          | Day 8         | MA          | 37.2        | None         | None    | None     | None       | None     | None   |
| CV01KP009  | 100 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A         | None         | None    | None     | None       | None     | None   |
| CV01KP009  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A         | None         | None    | None     | None       | None     | None   |
| CV01KP009  | 100 µg (18-55 years) | 02          | Day 1         | MA          | 38.4 (Mild) | Moderate     | None    | Moderate | None       | Mild     | Mild   |
| CV01KP009  | 100 µg (18-55 years) | 02          | Day 2         | MA          | 38.2 (Mild) | Mild         | None    | Mild     | None       | None     | Mild   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP009  | 100 µg<br>(18-55 years) | 02          | Day 3         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP009  | 100 µg<br>(18-55 years) | 02          | Day 4         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP009  | 100 µg<br>(18-55 years) | 02          | Day 5         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP009  | 100 µg<br>(18-55 years) | 02          | Day 6         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP009  | 100 µg<br>(18-55 years) | 02          | Day 7         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP009  | 100 µg<br>(18-55 years) | 02          | Day 8         | MA          | 37.4       | None         | None    | None    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years)  | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years)  | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years)  | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years)  | 01          | Day 2         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years)  | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years)  | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years)  | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years)  | 01          | Day 6         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP010  | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.6       | None         | None    | Mild    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37         | None         | Mild    | Mild    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP010  | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP011  | 25 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP011  | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP01<br>1 | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>1 | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>1 | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>1 | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>1 | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>1 | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>1 | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>1 | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>1 | 25 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>1 | 25 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>1 | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>1 | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>1 | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>1 | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|--------|
| CV01KP01<br>1 | 25 µg<br>(18-55 years)  | 02          | Day 5         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01KP01<br>1 | 25 µg<br>(18-55 years)  | 02          | Day 6         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01KP01<br>1 | 25 µg<br>(18-55 years)  | 02          | Day 7         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01KP01<br>1 | 25 µg<br>(18-55 years)  | 02          | Day 8         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 01          | Day 1         | MA          | 37.6       | Mild         | Moderate | None    | None       | None     | None   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 01          | Day 2         | MA          | 37.2       | Mild         | Mild     | None    | None       | None     | None   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.9       | None         | None     | None    | None       | None     | None   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.8       | None         | None     | None    | None       | None     | None   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 01          | Day 5         | MA          | 37         | None         | None     | None    | None       | None     | None   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.8       | None         | None     | None    | None       | None     | None   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 01          | Day 7         | MA          | 37.2       | None         | None     | None    | None       | None     | None   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C)  | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|-------------|--------------|---------|---------|------------|----------|--------|
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 02          | Day 1         | MA          | 37.1        | None         | Mild    | None    | None       | None     | None   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 02          | Day 2         | MA          | 38.2 (Mild) | Mild         | Mild    | None    | None       | Moderate | Mild   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 02          | Day 3         | MA          | 37.4        | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 02          | Day 4         | MA          | 37.4        | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 02          | Day 5         | MA          | 37.1        | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 02          | Day 6         | MA          | 37.1        | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.8        | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>2 | 100 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.8        | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A         | None         | None    | None    | None       | Mild     | None   |
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 01          | Day 1         | MA          | 37          | None         | None    | None    | None       | Mild     | None   |
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 01          | Day 2         | MA          | 37.1        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 01          | Day 3         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 01          | Day 4         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 01          | Day 6         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 01          | Day 7         | MA          | 37.4       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 01          | Day 8         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 02          | Day 1         | MA          | 37.4       | Mild         | None    | None    | None       | None     | None   |
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37.1       | None         | Mild    | None    | None       | None     | None   |
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 02          | Day 3         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 02          | Day 4         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 02          | Day 5         | MA          | 37.4       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 02          | Day 6         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 02          | Day 7         | MA          | 37.4       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>4 | 100 µg<br>(18-55 years) | 02          | Day 8         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years)  | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years)  | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years)  | 01          | Day 1         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years)  | 01          | Day 2         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years)  | 01          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years)  | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years)  | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years)  | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years)  | 01          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years)  | 01          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years)  | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years)  | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP01<br>5 | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>5 | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>8 | 25 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>8 | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>8 | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>8 | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>8 | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>8 | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP01<br>8 | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>8 | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>8 | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP01<br>8 | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37.2       | None         | Mild    | None    | None       | Moderate | Mild   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>3 | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>4 | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.7       | None         | Mild    | None    | None       | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37.6       | Mild         | Mild    | Mild    | Moderate   | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>6 | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | 37.5       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | 37.4       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | 37.4       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | 37.5       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | 37.6       | None         | None    | None    | None       | None     | None   |
| CV01KP02<br>7 | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | 37.4       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea   |
|------------|-------------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|----------|
| CV01KP028  | 25 µg<br>(18-55 years)  | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None     |
| CV01KP028  | 25 µg<br>(18-55 years)  | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None     |
| CV01KP028  | 25 µg<br>(18-55 years)  | 01          | Day 1         | MA          | 37.1       | None         | None     | None    | None       | None     | None     |
| CV01KP028  | 25 µg<br>(18-55 years)  | 01          | Day 2         | MA          | 36.8       | None         | Moderate | None    | None       | Mild     | Moderate |
| CV01KP028  | 25 µg<br>(18-55 years)  | 01          | Day 3         | MA          | 37         | None         | None     | None    | None       | None     | None     |
| CV01KP028  | 25 µg<br>(18-55 years)  | 01          | Day 4         | MA          | 36.7       | None         | None     | None    | None       | None     | None     |
| CV01KP028  | 25 µg<br>(18-55 years)  | 01          | Day 5         | MA          | 36.6       | None         | None     | None    | None       | None     | None     |
| CV01KP028  | 25 µg<br>(18-55 years)  | 01          | Day 6         | MA          | 36.9       | None         | None     | None    | None       | None     | None     |
| CV01KP028  | 25 µg<br>(18-55 years)  | 01          | Day 7         | MA          | 36.7       | None         | None     | None    | None       | None     | None     |
| CV01KP028  | 25 µg<br>(18-55 years)  | 01          | Day 8         | MA          | 36.6       | None         | None     | None    | None       | None     | None     |
| CV01KP030  | 250 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None     |
| CV01KP030  | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None     |
| CV01KP030  | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.9       | None         | None     | None    | None       | None     | None     |
| CV01KP030  | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | 37.3       | None         | None     | None    | None       | None     | None     |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C)  | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|-------------|--------------|---------|---------|------------|----------|--------|
| CV01KP030  | 250 µg (18-55 years) | 01          | Day 3         | MA          | 37.1        | None         | None    | None    | None       | None     | None   |
| CV01KP030  | 250 µg (18-55 years) | 01          | Day 4         | MA          | 37.2        | None         | None    | None    | None       | None     | None   |
| CV01KP030  | 250 µg (18-55 years) | 01          | Day 5         | MA          | 37.1        | None         | None    | None    | None       | None     | None   |
| CV01KP030  | 250 µg (18-55 years) | 01          | Day 6         | MA          | 37.3        | None         | None    | None    | None       | None     | None   |
| CV01KP030  | 250 µg (18-55 years) | 01          | Day 7         | MA          | 37          | None         | None    | None    | None       | None     | None   |
| CV01KP030  | 250 µg (18-55 years) | 01          | Day 8         | MA          | 37.5        | None         | None    | None    | None       | None     | None   |
| CV01KP030  | 250 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01KP030  | 250 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01KP030  | 250 µg (18-55 years) | 02          | Day 1         | MA          | 37.4        | None         | None    | None    | None       | None     | None   |
| CV01KP030  | 250 µg (18-55 years) | 02          | Day 2         | MA          | 38.3 (Mild) | Mild         | None    | Mild    | None       | Mild     | None   |
| CV01KP030  | 250 µg (18-55 years) | 02          | Day 3         | MA          | 37.3        | None         | None    | None    | None       | None     | None   |
| CV01KP030  | 250 µg (18-55 years) | 02          | Day 4         | MA          | 37.4        | None         | None    | None    | None       | None     | None   |
| CV01KP030  | 250 µg (18-55 years) | 02          | Day 5         | MA          | 37.6        | None         | None    | None    | None       | None     | None   |
| CV01KP030  | 250 µg (18-55 years) | 02          | Day 6         | MA          | 37.3        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP030  | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP030  | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Day 1         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Day 7         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP031  | 25 µg<br>(18-55 years)  | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP031  | 25 µg<br>(18-55 years)  | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|----------|----------|------------|----------|--------|
| CV01KP03<br>1 | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP03<br>1 | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37.6       | None         | Moderate | Moderate | Moderate   | None     | None   |
| CV01KP03<br>1 | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP03<br>1 | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP03<br>1 | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.6       | None         | None     | None     | None       | None     | None   |
| CV01KP03<br>1 | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP03<br>1 | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.9       | None         | None     | None     | None       | None     | None   |
| CV01KP03<br>1 | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.8       | None         | None     | None     | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.9       | None         | None     | None     | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.8       | None         | None     | None     | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>2 | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C)  | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|-------------|--------------|---------|---------|------------|----------|--------|
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.7        | None         | None    | None    | None       | Mild     | None   |
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.8        | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | 37.1        | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.9        | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | 37.2        | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.7        | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.8        | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.6        | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 02          | Day 1         | MA          | 38.4 (Mild) | Moderate     | None    | Mild    | None       | None     | None   |
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 02          | Day 2         | MA          | 38 (Mild)   | Mild         | None    | None    | Mild       | Mild     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.7       | None         | None    | None    | Mild       | Mild     | None   |
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 02          | Day 6         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>3 | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | 37.4       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 02          | Day 1         | MA          | 37.6       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37.5       | None         | Mild    | Mild    | None       | Moderate | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 02          | Day 3         | MA          | 37.3       | None         | None    | Mild    | None       | None     | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | 37.4       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 02          | Day 5         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 02          | Day 6         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>6 | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>7 | 250 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>7 | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP03<br>7 | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>7 | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | 37.4       | None         | None    | None    | None       | Mild     | None   |
| CV01KP03<br>7 | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>7 | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>7 | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>7 | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>7 | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | 37.4       | None         | None    | None    | None       | None     | None   |
| CV01KP03<br>7 | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP04<br>0 | 250 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP04<br>0 | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP04<br>0 | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP04<br>0 | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP04<br>0 | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP04<br>0 | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C)    | Feverishness | Fatigue | Myalgia  | Arthralgia | Headache | Nausea   |
|------------|----------------------|-------------|---------------|-------------|---------------|--------------|---------|----------|------------|----------|----------|
| CV01KP040  | 250 µg (18-55 years) | 01          | Day 5         | MA          | 36.7          | None         | None    | None     | None       | None     | None     |
| CV01KP040  | 250 µg (18-55 years) | 01          | Day 6         | MA          | 36.9          | None         | None    | None     | None       | None     | None     |
| CV01KP040  | 250 µg (18-55 years) | 01          | Day 7         | MA          | 36.6          | None         | None    | None     | None       | None     | None     |
| CV01KP040  | 250 µg (18-55 years) | 01          | Day 8         | MA          | 36.7          | None         | None    | None     | None       | None     | None     |
| CV01KP040  | 250 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A           | None         | None    | None     | None       | None     | None     |
| CV01KP040  | 250 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A           | None         | None    | None     | None       | None     | None     |
| CV01KP040  | 250 µg (18-55 years) | 02          | Day 1         | MA          | 37.3          | Severe       | Mild    | Mild     | None       | Mild     | None     |
| CV01KP040  | 250 µg (18-55 years) | 02          | Day 2         | MA          | 39.6 (Severe) | Severe       | Severe  | Moderate | Mild       | Severe   | Moderate |
| CV01KP040  | 250 µg (18-55 years) | 02          | Day 3         | MA          | 37.1          | None         | Mild    | None     | None       | Mild     | None     |
| CV01KP040  | 250 µg (18-55 years) | 02          | Day 4         | MA          | 36.8          | None         | Mild    | None     | None       | None     | None     |
| CV01KP040  | 250 µg (18-55 years) | 02          | Day 5         | MA          | 36.7          | None         | Mild    | None     | None       | None     | None     |
| CV01KP040  | 250 µg (18-55 years) | 02          | Day 6         | MA          | 37.1          | None         | Mild    | None     | None       | None     | None     |
| CV01KP040  | 250 µg (18-55 years) | 02          | Day 7         | MA          | 37.1          | None         | None    | None     | None       | None     | None     |
| CV01KP040  | 250 µg (18-55 years) | 02          | Day 8         | MA          | 37.1          | None         | None    | None     | None       | None     | None     |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C)         | Feverishness | Fatigue | Myalgia  | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|--------------------|--------------|---------|----------|------------|----------|--------|
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A                | None         | None    | None     | None       | None     | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A                | None         | None    | None     | None       | None     | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | 37.4               | Mild         | Mild    | None     | None       | Moderate | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.7               | None         | None    | None     | None       | Mild     | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.7               | None         | None    | None     | None       | Mild     | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.7               | None         | None    | None     | None       | None     | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.7               | None         | None    | None     | None       | None     | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.7               | None         | None    | None     | None       | None     | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.7               | None         | None    | None     | None       | None     | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.7               | None         | None    | None     | None       | None     | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A                | None         | None    | None     | None       | None     | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A                | None         | None    | None     | None       | None     | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 02          | Day 1         | MA          | 37.8               | None         | Mild    | None     | None       | None     | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 02          | Day 2         | MA          | 38.8<br>(Moderate) | Severe       | Severe  | Moderate | Moderate   | Moderate | Mild   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.8       | None         | Mild    | None    | None       | Mild     | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.7       | None         | Mild    | None    | None       | None     | None   |
| CV01KP04<br>1 | 250 µg<br>(18-55 years) | 02          | Day 10        | MA          | N/A        |              | Mild    |         |            |          |        |
| CV01KP04<br>8 | 250 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP04<br>8 | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP04<br>8 | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP04<br>8 | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP04<br>8 | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP04<br>8 | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP04<br>8 | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | 37.5       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C)      | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|-----------------|--------------|---------|---------|------------|----------|--------|
| CV01KP048  | 250 µg (18-55 years) | 01          | Day 6         | MA          | 37.3            | None         | None    | None    | None       | None     | None   |
| CV01KP048  | 250 µg (18-55 years) | 01          | Day 7         | MA          | 37.3            | None         | None    | None    | None       | None     | None   |
| CV01KP048  | 250 µg (18-55 years) | 01          | Day 8         | MA          | 37.2            | None         | None    | None    | None       | None     | None   |
| CV01KP048  | 250 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A             | None         | None    | None    | None       | None     | None   |
| CV01KP048  | 250 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A             | None         | None    | None    | None       | None     | None   |
| CV01KP048  | 250 µg (18-55 years) | 02          | Day 1         | MA          | 37.2            | None         | None    | None    | None       | Mild     | None   |
| CV01KP048  | 250 µg (18-55 years) | 02          | Day 2         | MA          | 38.6 (Moderate) | Severe       | None    | Severe  | None       | None     | Severe |
| CV01KP048  | 250 µg (18-55 years) | 02          | Day 3         | MA          | 37.2            | None         | None    | None    | None       | None     | None   |
| CV01KP048  | 250 µg (18-55 years) | 02          | Day 4         | MA          | 37.8            | None         | None    | None    | None       | None     | None   |
| CV01KP048  | 250 µg (18-55 years) | 02          | Day 5         | MA          | 36.8            | None         | None    | None    | None       | None     | None   |
| CV01KP048  | 250 µg (18-55 years) | 02          | Day 6         | MA          | 37.3            | None         | None    | None    | None       | None     | None   |
| CV01KP048  | 250 µg (18-55 years) | 02          | Day 7         | MA          | 37.1            | None         | None    | None    | None       | None     | None   |
| CV01KP048  | 250 µg (18-55 years) | 02          | Day 8         | MA          | 37.3            | None         | None    | None    | None       | None     | None   |
| CV01KP049  | 250 µg (18-55 years) | 01          | Pre-Dose      | Clinic      | N/A             | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|----------|----------|------------|----------|--------|
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | Mild     | None     | None       | None     | None   |
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.8       | None         | Mild     | Mild     | None       | Mild     | None   |
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.8       | None         | Mild     | Mild     | None       | Moderate | None   |
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.7       | None         | Mild     | None     | None       | Mild     | None   |
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | N/A        | None         | None     | None     | None       | None     | None   |
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.6       | None         | None     | None     | None       | None     | None   |
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 02          | Day 1         | MA          | 37.1       | None         | Moderate | Mild     | None       | Moderate | None   |
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 02          | Day 2         | MA          | 36.7       | Mild         | Moderate | Moderate | Moderate   | Mild     | None   |
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.7       | None         | Mild     | Mild     | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea   |
|---------------|-------------------------|-------------|---------------|-------------|------------|--------------|----------|----------|------------|----------|----------|
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.7       | None         | None     | None     | None       | Mild     | None     |
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.7       | None         | None     | None     | None       | None     | None     |
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.7       | None         | None     | None     | None       | None     | None     |
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | N/A        | Not Done     | Not Done | Not Done | Not Done   | Not Done | Not Done |
| CV01KP04<br>9 | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.7       | None         | None     | None     | None       | None     | None     |
| CV01KP05<br>3 | 250 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None     |
| CV01KP05<br>3 | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | None       | None     | None     |
| CV01KP05<br>3 | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | 37.3       | Mild         | Moderate | None     | None       | None     | None     |
| CV01KP05<br>3 | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | 37.7       | None         | Mild     | Mild     | None       | None     | None     |
| CV01KP05<br>3 | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | 37.1       | None         | None     | None     | None       | None     | None     |
| CV01KP05<br>3 | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.9       | None         | None     | None     | None       | None     | None     |
| CV01KP05<br>3 | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.7       | None         | None     | None     | None       | None     | None     |
| CV01KP05<br>3 | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.7       | None         | None     | None     | None       | None     | None     |
| CV01KP05<br>3 | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.7       | None         | None     | None     | None       | Mild     | None     |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C)  | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|------------|----------------------|-------------|---------------|-------------|-------------|--------------|----------|---------|------------|----------|--------|
| CV01KP053  | 250 µg (18-55 years) | 01          | Day 8         | MA          | 36.8        | None         | None     | None    | None       | None     | None   |
| CV01KP053  | 250 µg (18-55 years) | 02          | Pre-Dose      | Clinic      | N/A         | None         | None     | None    | None       | None     | None   |
| CV01KP053  | 250 µg (18-55 years) | 02          | Post-Dose     | Clinic      | N/A         | None         | None     | None    | None       | None     | None   |
| CV01KP053  | 250 µg (18-55 years) | 02          | Day 1         | MA          | 38.2 (Mild) | Moderate     | Moderate | Mild    | None       | None     | None   |
| CV01KP053  | 250 µg (18-55 years) | 02          | Day 2         | MA          | 38.2 (Mild) | Moderate     | Moderate | Mild    | None       | Mild     | None   |
| CV01KP053  | 250 µg (18-55 years) | 02          | Day 3         | MA          | 37.2        | None         | Mild     | None    | None       | None     | None   |
| CV01KP053  | 250 µg (18-55 years) | 02          | Day 4         | MA          | 37.1        | None         | Mild     | None    | None       | None     | None   |
| CV01KP053  | 250 µg (18-55 years) | 02          | Day 5         | MA          | 36.7        | None         | None     | None    | None       | None     | None   |
| CV01KP053  | 250 µg (18-55 years) | 02          | Day 6         | MA          | 37.1        | None         | None     | None    | None       | Mild     | None   |
| CV01KP053  | 250 µg (18-55 years) | 02          | Day 7         | MA          | 37.1        | None         | None     | None    | None       | None     | None   |
| CV01KP053  | 250 µg (18-55 years) | 02          | Day 8         | MA          | 36.7        | None         | None     | None    | None       | None     | None   |
| CV01KP059  | 25 µg (≥71 years)    | 01          | Pre-Dose      | Clinic      | N/A         | None         | None     | None    | None       | None     | None   |
| CV01KP059  | 25 µg (≥71 years)    | 01          | Post-Dose     | Clinic      | N/A         | None         | None     | None    | None       | None     | None   |
| CV01KP059  | 25 µg (≥71 years)    | 01          | Day 1         | MA          | 36.6        | None         | Mild     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|-------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP059  | 25 µg (≥71 years) | 01          | Day 2         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP059  | 25 µg (≥71 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP059  | 25 µg (≥71 years) | 01          | Day 4         | MA          | 37.6       | None         | None    | None    | None       | None     | None   |
| CV01KP059  | 25 µg (≥71 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP059  | 25 µg (≥71 years) | 01          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | Mild     | None   |
| CV01KP059  | 25 µg (≥71 years) | 01          | Day 7         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP059  | 25 µg (≥71 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP059  | 25 µg (≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP059  | 25 µg (≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP059  | 25 µg (≥71 years) | 02          | Day 1         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP059  | 25 µg (≥71 years) | 02          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP059  | 25 µg (≥71 years) | 02          | Day 3         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01KP059  | 25 µg (≥71 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP059  | 25 µg (≥71 years) | 02          | Day 5         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|-------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP059  | 25 µg (≥71 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | Mild     | None   |
| CV01KP059  | 25 µg (≥71 years) | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP059  | 25 µg (≥71 years) | 02          | Day 8         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 01          | Day 1         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 01          | Day 2         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 01          | Day 4         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 01          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 01          | Day 6         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 01          | Day 7         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 01          | Day 8         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|-------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP060  | 25 µg (≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 02          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 02          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 02          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 02          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 02          | Day 5         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 02          | Day 6         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 02          | Day 7         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP060  | 25 µg (≥71 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP061  | 25 µg (≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP061  | 25 µg (≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP061  | 25 µg (≥71 years) | 01          | Day 1         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01KP061  | 25 µg (≥71 years) | 01          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP061  | 25 µg (≥71 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP06<br>1 | 25 µg<br>(≥71 years) | 01          | Day 4         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>1 | 25 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | Mild    | None       | None     | None   |
| CV01KP06<br>1 | 25 µg<br>(≥71 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>1 | 25 µg<br>(≥71 years) | 01          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>1 | 25 µg<br>(≥71 years) | 01          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>1 | 25 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>1 | 25 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>1 | 25 µg<br>(≥71 years) | 02          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>1 | 25 µg<br>(≥71 years) | 02          | Day 2         | MA          | 36.6       | None         | None    | Mild    | None       | Mild     | None   |
| CV01KP06<br>1 | 25 µg<br>(≥71 years) | 02          | Day 3         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>1 | 25 µg<br>(≥71 years) | 02          | Day 4         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>1 | 25 µg<br>(≥71 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>1 | 25 µg<br>(≥71 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>1 | 25 µg<br>(≥71 years) | 02          | Day 7         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP06<br>1 | 25 µg<br>(≥71 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 01          | Day 1         | MA          | 36.7       | None         | Mild    | Mild    | Mild       | Mild     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 01          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 01          | Day 4         | MA          | 36.8       | None         | Mild    | None    | None       | None     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.7       | None         | Mild    | None    | None       | None     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 01          | Day 6         | MA          | 36.8       | None         | Mild    | None    | None       | None     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 01          | Day 7         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 01          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 02          | Day 1         | MA          | 37.5       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 02          | Day 2         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 02          | Day 3         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 02          | Day 4         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 02          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 02          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 02          | Day 7         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>2 | 25 µg<br>(≥71 years) | 02          | Day 8         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>3 | 25 µg<br>(≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>3 | 25 µg<br>(≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>3 | 25 µg<br>(≥71 years) | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>3 | 25 µg<br>(≥71 years) | 01          | Day 2         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>3 | 25 µg<br>(≥71 years) | 01          | Day 3         | MA          | 37.2       | None         | None    | Mild    | None       | None     | None   |
| CV01KP06<br>3 | 25 µg<br>(≥71 years) | 01          | Day 4         | MA          | 37.2       | None         | None    | Mild    | None       | None     | None   |
| CV01KP06<br>3 | 25 µg<br>(≥71 years) | 01          | Day 5         | MA          | 37.3       | None         | None    | Mild    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|-------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP063  | 25 µg (≥71 years) | 01          | Day 6         | MA          | 37.2       | None         | None    | Mild    | None       | None     | None   |
| CV01KP063  | 25 µg (≥71 years) | 01          | Day 7         | MA          | 36.9       | None         | None    | Mild    | None       | None     | None   |
| CV01KP063  | 25 µg (≥71 years) | 01          | Day 8         | MA          | 37.2       | None         | None    | Mild    | None       | None     | None   |
| CV01KP063  | 25 µg (≥71 years) | 01          | Day 14        | MA          | N/A        |              |         | Mild    |            |          |        |
| CV01KP063  | 25 µg (≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP063  | 25 µg (≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP063  | 25 µg (≥71 years) | 02          | Day 1         | MA          | 36.8       | None         | Mild    | None    | None       | None     | None   |
| CV01KP063  | 25 µg (≥71 years) | 02          | Day 2         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP063  | 25 µg (≥71 years) | 02          | Day 3         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP063  | 25 µg (≥71 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP063  | 25 µg (≥71 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP063  | 25 µg (≥71 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP063  | 25 µg (≥71 years) | 02          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP063  | 25 µg (≥71 years) | 02          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group  | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|--------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP064  | 100 µg (≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP064  | 100 µg (≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP064  | 100 µg (≥71 years) | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP064  | 100 µg (≥71 years) | 01          | Day 2         | MA          | 36.5       | None         | Mild    | Mild    | None       | None     | None   |
| CV01KP064  | 100 µg (≥71 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP064  | 100 µg (≥71 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP064  | 100 µg (≥71 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP064  | 100 µg (≥71 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP064  | 100 µg (≥71 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP064  | 100 µg (≥71 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP064  | 100 µg (≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP064  | 100 µg (≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP064  | 100 µg (≥71 years) | 02          | Day 1         | MA          | 36.7       | None         | Mild    | None    | None       | None     | None   |
| CV01KP064  | 100 µg (≥71 years) | 02          | Day 2         | MA          | 37.5       | None         | Mild    | Mild    | Mild       | Mild     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group     | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP06<br>4 | 100 µg<br>(≥71 years) | 02          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>4 | 100 µg<br>(≥71 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>4 | 100 µg<br>(≥71 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>4 | 100 µg<br>(≥71 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>4 | 100 µg<br>(≥71 years) | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>4 | 100 µg<br>(≥71 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years)  | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years)  | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years)  | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years)  | 01          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years)  | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years)  | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years)  | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years)  | 01          | Day 6         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP06<br>5 | 25 µg<br>(≥71 years) | 01          | Day 7         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years) | 01          | Day 8         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years) | 02          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years) | 02          | Day 2         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years) | 02          | Day 3         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years) | 02          | Day 4         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years) | 02          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years) | 02          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years) | 02          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>5 | 25 µg<br>(≥71 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>6 | 25 µg<br>(≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>6 | 25 µg<br>(≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP06<br>6 | 25 µg<br>(≥71 years) | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | Mild     | None   |
| CV01KP06<br>6 | 25 µg<br>(≥71 years) | 01          | Day 2         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>6 | 25 µg<br>(≥71 years) | 01          | Day 3         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>6 | 25 µg<br>(≥71 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>6 | 25 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>6 | 25 µg<br>(≥71 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>6 | 25 µg<br>(≥71 years) | 01          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>6 | 25 µg<br>(≥71 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>6 | 25 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>6 | 25 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>6 | 25 µg<br>(≥71 years) | 02          | Day 1         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>6 | 25 µg<br>(≥71 years) | 02          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>6 | 25 µg<br>(≥71 years) | 02          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>6 | 25 µg<br>(≥71 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group     | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP06<br>6 | 25 µg<br>(≥71 years)  | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>6 | 25 µg<br>(≥71 years)  | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>6 | 25 µg<br>(≥71 years)  | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>6 | 25 µg<br>(≥71 years)  | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 01          | Day 1         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 01          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 01          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 01          | Day 6         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group     | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 02          | Day 1         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 02          | Day 2         | MA          | 37         | None         | Mild    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 02          | Day 3         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>7 | 100 µg<br>(≥71 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>8 | 25 µg<br>(≥71 years)  | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>8 | 25 µg<br>(≥71 years)  | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>8 | 25 µg<br>(≥71 years)  | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP06<br>8 | 25 µg<br>(≥71 years)  | 01          | Day 2         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|-------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP068  | 25 µg (≥71 years) | 01          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP068  | 25 µg (≥71 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP068  | 25 µg (≥71 years) | 01          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP068  | 25 µg (≥71 years) | 01          | Day 6         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP068  | 25 µg (≥71 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP068  | 25 µg (≥71 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP068  | 25 µg (≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP068  | 25 µg (≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP068  | 25 µg (≥71 years) | 02          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP068  | 25 µg (≥71 years) | 02          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP068  | 25 µg (≥71 years) | 02          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP068  | 25 µg (≥71 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP068  | 25 µg (≥71 years) | 02          | Day 5         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP068  | 25 µg (≥71 years) | 02          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|-------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP068  | 25 µg (≥71 years) | 02          | Day 7         | MA          | 35         | None         | None    | None    | None       | None     | None   |
| CV01KP068  | 25 µg (≥71 years) | 02          | Day 8         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years) | 01          | Day 1         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years) | 01          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years) | 01          | Day 3         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years) | 01          | Day 4         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years) | 01          | Day 5         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years) | 01          | Day 6         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years) | 01          | Day 8         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group  | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|--------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP069  | 25 µg (≥71 years)  | 02          | Day 1         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years)  | 02          | Day 2         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years)  | 02          | Day 3         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years)  | 02          | Day 4         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years)  | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years)  | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years)  | 02          | Day 7         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP069  | 25 µg (≥71 years)  | 02          | Day 8         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP071  | 100 µg (≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP071  | 100 µg (≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP071  | 100 µg (≥71 years) | 01          | Day 1         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP071  | 100 µg (≥71 years) | 01          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP071  | 100 µg (≥71 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP071  | 100 µg (≥71 years) | 01          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group     | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP07<br>1 | 100 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>1 | 100 µg<br>(≥71 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>1 | 100 µg<br>(≥71 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>1 | 100 µg<br>(≥71 years) | 01          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>1 | 100 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>1 | 100 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>1 | 100 µg<br>(≥71 years) | 02          | Day 1         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>1 | 100 µg<br>(≥71 years) | 02          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>1 | 100 µg<br>(≥71 years) | 02          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>1 | 100 µg<br>(≥71 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>1 | 100 µg<br>(≥71 years) | 02          | Day 5         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>1 | 100 µg<br>(≥71 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>1 | 100 µg<br>(≥71 years) | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>1 | 100 µg<br>(≥71 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP07<br>2 | 25 µg<br>(≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>2 | 25 µg<br>(≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>2 | 25 µg<br>(≥71 years) | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>2 | 25 µg<br>(≥71 years) | 01          | Day 2         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>2 | 25 µg<br>(≥71 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>2 | 25 µg<br>(≥71 years) | 01          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>2 | 25 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>2 | 25 µg<br>(≥71 years) | 01          | Day 6         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>2 | 25 µg<br>(≥71 years) | 01          | Day 7         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>2 | 25 µg<br>(≥71 years) | 01          | Day 8         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>2 | 25 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>2 | 25 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>2 | 25 µg<br>(≥71 years) | 02          | Day 1         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>2 | 25 µg<br>(≥71 years) | 02          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group     | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP07<br>2 | 25 µg<br>(≥71 years)  | 02          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>2 | 25 µg<br>(≥71 years)  | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>2 | 25 µg<br>(≥71 years)  | 02          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>2 | 25 µg<br>(≥71 years)  | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>2 | 25 µg<br>(≥71 years)  | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>2 | 25 µg<br>(≥71 years)  | 02          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 01          | Day 1         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 01          | Day 2         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 01          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group     | Dose Number | Post Dose Day | Assessment* | Fever (°C)  | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-----------------------|-------------|---------------|-------------|-------------|--------------|----------|---------|------------|----------|--------|
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 01          | Day 7         | MA          | 36.7        | None         | None     | None    | None       | None     | None   |
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A         | None         | None     | None    | None       | None     | None   |
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A         | None         | None     | None    | None       | None     | None   |
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 02          | Day 1         | MA          | 38.1 (Mild) | Mild         | Moderate | Mild    | None       | Moderate | Mild   |
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 02          | Day 2         | MA          | 37.8        | None         | Moderate | None    | None       | Moderate | None   |
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 02          | Day 3         | MA          | 37.1        | None         | None     | None    | None       | Mild     | None   |
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 02          | Day 4         | MA          | 36.6        | None         | None     | None    | None       | None     | None   |
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 02          | Day 5         | MA          | 36.7        | None         | None     | None    | None       | None     | None   |
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 02          | Day 6         | MA          | 36.6        | None         | None     | None    | None       | None     | None   |
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 02          | Day 7         | MA          | 36.7        | None         | None     | None    | None       | None     | None   |
| CV01KP07<br>3 | 100 µg<br>(≥71 years) | 02          | Day 8         | MA          | 36.7        | None         | None     | None    | None       | None     | None   |
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 01          | Pre-Dose      | Clinic      | N/A         | None         | None     | None    | None       | None     | None   |
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 01          | Post-Dose     | Clinic      | N/A         | None         | None     | None    | None       | None     | None   |
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 01          | Day 1         | MA          | 36.7        | None         | None     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group     | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea |
|---------------|-----------------------|-------------|---------------|-------------|------------|--------------|----------|----------|------------|----------|--------|
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 01          | Day 2         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 01          | Day 3         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 01          | Day 4         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 01          | Day 6         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 01          | Day 7         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 01          | Day 8         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 02          | Day 1         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 02          | Day 2         | MA          | 37.4       | Mild         | Moderate | Moderate | None       | None     | None   |
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 02          | Day 3         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 02          | Day 4         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 02          | Day 5         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group     | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 02          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>5 | 100 µg<br>(≥71 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 01          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 01          | Day 3         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 01          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 01          | Day 6         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 01          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 01          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group     | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 02          | Day 1         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 02          | Day 2         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 02          | Day 3         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 02          | Day 4         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>6 | 100 µg<br>(≥71 years) | 02          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 01          | Day 1         | MA          | 37.1       | None         | Mild    | None    | None       | None     | None   |
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 01          | Day 2         | MA          | 36.7       | None         | Mild    | None    | None       | None     | None   |
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 01          | Day 3         | MA          | 36.8       | None         | Mild    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group     | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 01          | Day 7         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 01          | Day 8         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 02          | Day 1         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 02          | Day 2         | MA          | 37.6       | Moderate     | Severe  | Mild    | None       | Mild     | None   |
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 02          | Day 3         | MA          | 36.7       | None         | Mild    | None    | None       | None     | None   |
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 02          | Day 4         | MA          | 37.1       | None         | Mild    | None    | None       | None     | None   |
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 02          | Day 7         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group     | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP07<br>7 | 100 µg<br>(≥71 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 01          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 01          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 01          | Day 4         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 01          | Day 7         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 01          | Day 8         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 02          | Day 1         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group     | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 02          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 02          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 02          | Day 4         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 02          | Day 6         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP07<br>8 | 100 µg<br>(≥71 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 01          | Day 2         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 01          | Day 3         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 01          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group     | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-----------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|--------|
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 01          | Day 6         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 01          | Day 7         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 01          | Day 8         | MA          | 36.8       | None         | None     | None    | None       | None     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 02          | Day 1         | MA          | 36.6       | None         | None     | None    | None       | None     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 02          | Day 2         | MA          | 37.6       | Mild         | Moderate | Mild    | None       | Mild     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 02          | Day 3         | MA          | 36.8       | None         | None     | Mild    | None       | None     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 02          | Day 4         | MA          | 37         | None         | None     | None    | None       | None     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 02          | Day 5         | MA          | 36.6       | None         | None     | None    | None       | None     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 02          | Day 6         | MA          | 37.2       | None         | None     | None    | None       | None     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 02          | Day 7         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01KP08<br>1 | 100 µg<br>(≥71 years) | 02          | Day 8         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01KP08<br>5 | 100 µg<br>(≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group     | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|-----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP08<br>5 | 100 µg<br>(≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>5 | 100 µg<br>(≥71 years) | 01          | Day 1         | MA          | 36.7       | None         | Mild    | Mild    | None       | None     | None   |
| CV01KP08<br>5 | 100 µg<br>(≥71 years) | 01          | Day 2         | MA          | 36.7       | Mild         | Mild    | None    | None       | None     | None   |
| CV01KP08<br>5 | 100 µg<br>(≥71 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>5 | 100 µg<br>(≥71 years) | 01          | Day 4         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>5 | 100 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>5 | 100 µg<br>(≥71 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>5 | 100 µg<br>(≥71 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>5 | 100 µg<br>(≥71 years) | 01          | Day 8         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>5 | 100 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>5 | 100 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>5 | 100 µg<br>(≥71 years) | 02          | Day 1         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>5 | 100 µg<br>(≥71 years) | 02          | Day 2         | MA          | 37.4       | None         | Mild    | Mild    | Mild       | None     | None   |
| CV01KP08<br>5 | 100 µg<br>(≥71 years) | 02          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP08<br>5 | 100 µg<br>(≥71 years)  | 02          | Day 4         | MA          | 36.7       | None         | Mild    | None    | Mild       | None     | None   |
| CV01KP08<br>5 | 100 µg<br>(≥71 years)  | 02          | Day 5         | MA          | 37.2       | None         | None    | Mild    | None       | None     | None   |
| CV01KP08<br>5 | 100 µg<br>(≥71 years)  | 02          | Day 6         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>5 | 100 µg<br>(≥71 years)  | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP08<br>5 | 100 µg<br>(≥71 years)  | 02          | Day 8         | MA          | 36.7       | None         | Mild    | None    | None       | None     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.7       | None         | Mild    | Mild    | None       | None     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.8       | None         | Mild    | None    | None       | None     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37.3       | None         | None    | Mild    | None       | Mild     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>2 | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.7       | None         | Mild    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|----------|----------|------------|----------|--------|
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37.7       | None         | Moderate | Moderate | None       | Moderate | None   |
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>4 | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.7       | Moderate     | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>5 | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | Mild    | None    | None       | None     | None   |
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | 37.1       | None         | Mild    | None    | None       | None     | None   |
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37.9       | None         | Mild    | Mild    | None       | Mild     | None   |
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | Mild     | None   |
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|--------|
| CV01KP09<br>6 | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.7       | None         | None     | None    | None       | Mild     | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.5       | None         | Moderate | None    | None       | Mild     | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.6       | None         | Mild     | None    | None       | Mild     | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | 37.1       | None         | None     | None    | None       | None     | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.6       | None         | None     | None    | None       | None     | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.7       | None         | Mild     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia  | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|----------|----------|------------|----------|--------|
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37.7       | None         | Moderate | Moderate | None       | Moderate | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.7       | None         | Mild     | Mild     | None       | None     | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.5       | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.6       | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>7 | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.7       | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.7       | None         | Mild     | None     | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | 36.8       | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | 37.4       | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | 37         | None         | None     | None     | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | 37.6       | None         | None     | None     | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.7       | None         | Mild    | None    | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP09<br>8 | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01KP10<br>1 | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR00<br>2 | 50 µg<br>(≥71 years)   | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR00<br>2 | 50 µg<br>(≥71 years)   | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR00<br>2 | 50 µg<br>(≥71 years)   | 01          | Day 1         | MA          | 36         | None         | None    | None    | None       | None     | None   |
| CV01VR00<br>2 | 50 µg<br>(≥71 years)   | 01          | Day 2         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01VR00<br>2 | 50 µg<br>(≥71 years)   | 01          | Day 3         | MA          | 36.1       | None         | None    | None    | None       | None     | None   |
| CV01VR00<br>2 | 50 µg<br>(≥71 years)   | 01          | Day 4         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR00<br>2 | 50 µg<br>(≥71 years)   | 01          | Day 5         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR00<br>2 | 50 µg<br>(≥71 years)   | 01          | Day 6         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR00<br>2 | 50 µg<br>(≥71 years)   | 01          | Day 7         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group   | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|---------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR002  | 50 µg (≥71 years)   | 01          | Day 8         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR002  | 50 µg (≥71 years)   | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR002  | 50 µg (≥71 years)   | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR002  | 50 µg (≥71 years)   | 02          | Day 1         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR002  | 50 µg (≥71 years)   | 02          | Day 2         | MA          | 35.9       | None         | None    | None    | None       | None     | None   |
| CV01VR002  | 50 µg (≥71 years)   | 02          | Day 3         | MA          | 35.9       | None         | None    | None    | None       | None     | None   |
| CV01VR002  | 50 µg (≥71 years)   | 02          | Day 4         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR002  | 50 µg (≥71 years)   | 02          | Day 5         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR002  | 50 µg (≥71 years)   | 02          | Day 6         | MA          | 35.9       | None         | None    | None    | None       | None     | None   |
| CV01VR002  | 50 µg (≥71 years)   | 02          | Day 7         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR002  | 50 µg (≥71 years)   | 02          | Day 8         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR003  | 50 µg (56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR003  | 50 µg (56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR003  | 50 µg (56-70 years) | 01          | Day 1         | MA          | 36         | None         | None    | None    | None       | Mild     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR003  | 50 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR003  | 50 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR003  | 50 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR003  | 50 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR003  | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | 35.8       | None         | None    | None    | None       | None     | None   |
| CV01VR003  | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR003  | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR003  | 50 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR003  | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR003  | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.4       | None         | Mild    | None    | None       | Mild     | None   |
| CV01VR003  | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | 36.3       | None         | Mild    | None    | None       | None     | None   |
| CV01VR003  | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR003  | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR003  | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group   | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|---------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR003  | 50 µg (56-70 years) | 02          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR003  | 50 µg (56-70 years) | 02          | Day 7         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR003  | 50 µg (56-70 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 01          | Day 1         | MA          | 36.1       | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 01          | Day 2         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 01          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 01          | Day 4         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 01          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 01          | Day 6         | MA          | 37.3       | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 01          | Day 7         | MA          | 35.9       | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 01          | Day 8         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group   | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|---------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR004  | 50 µg (≥71 years)   | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 02          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 02          | Day 2         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 02          | Day 3         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 02          | Day 4         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 02          | Day 6         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 02          | Day 7         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR004  | 50 µg (≥71 years)   | 02          | Day 8         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR005  | 50 µg (56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR005  | 50 µg (56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR005  | 50 µg (56-70 years) | 01          | Day 1         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01VR005  | 50 µg (56-70 years) | 01          | Day 2         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR005  | 50 µg (56-70 years) | 01          | Day 3         | MA          | 36.1       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR005  | 50 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR005  | 50 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR005  | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR005  | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR005  | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.4       | None         | Mild    | None    | None       | None     | None   |
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | 36.5       | None         | Mild    | None    | None       | None     | None   |
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Day 1         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea   |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|----------|
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None     |
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | None     | None     |
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.9       | None         | None    | Mild    | None       | None     | None     |
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.7       | None         | None    | Mild    | None       | None     | None     |
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None     |
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Day 5         | MA          | 37.2       | None         | None    | None    | None       | None     | Moderate |
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.3       | None         | None    | None    | None       | None     | None     |
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None     |
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.4       | None         | None    | None    | None       | None     | None     |
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None     |
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None     |
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None     |
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None     |
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.9       | None         | None    | None    | None       | None     | None     |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01VR011  | 50 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR011  | 50 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR011  | 50 µg<br>(56-70 years) | 01          | Day 1         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01VR011  | 50 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR011  | 50 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR011  | 50 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR011  | 50 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR011  | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR011  | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C)  | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|-------------|--------------|---------|---------|------------|----------|--------|
| CV01VR01<br>1 | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.8        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>1 | 50 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>1 | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>1 | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.8        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>1 | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | 38.3 (Mild) | Mild         | Mild    | Mild    | None       | Mild     | None   |
| CV01VR01<br>1 | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.8        | None         | Mild    | None    | None       | None     | None   |
| CV01VR01<br>1 | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36.2        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>1 | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | 36.6        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>1 | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | 36.8        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>1 | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | 36.4        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>1 | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | 36.9        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>3 | 50 µg<br>(≥71 years)   | 01          | Pre-Dose      | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>3 | 50 µg<br>(≥71 years)   | 01          | Post-Dose     | Clinic      | N/A         | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>3 | 50 µg<br>(≥71 years)   | 01          | Day 1         | MA          | 36.9        | None         | Mild    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR01<br>3 | 50 µg<br>(≥71 years) | 01          | Day 2         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>3 | 50 µg<br>(≥71 years) | 01          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>3 | 50 µg<br>(≥71 years) | 01          | Day 4         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>3 | 50 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>3 | 50 µg<br>(≥71 years) | 01          | Day 6         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>3 | 50 µg<br>(≥71 years) | 01          | Day 7         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>3 | 50 µg<br>(≥71 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>3 | 50 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>3 | 50 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>3 | 50 µg<br>(≥71 years) | 02          | Day 1         | MA          | 36.8       | None         | Mild    | None    | None       | None     | None   |
| CV01VR01<br>3 | 50 µg<br>(≥71 years) | 02          | Day 2         | MA          | 37.3       | None         | Mild    | Mild    | None       | None     | None   |
| CV01VR01<br>3 | 50 µg<br>(≥71 years) | 02          | Day 3         | MA          | 36.5       | None         | None    | Mild    | None       | None     | None   |
| CV01VR01<br>3 | 50 µg<br>(≥71 years) | 02          | Day 4         | MA          | 36.8       | None         | None    | Mild    | None       | None     | None   |
| CV01VR01<br>3 | 50 µg<br>(≥71 years) | 02          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR01<br>3 | 50 µg<br>(≥71 years) | 02          | Day 6         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>3 | 50 µg<br>(≥71 years) | 02          | Day 7         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>3 | 50 µg<br>(≥71 years) | 02          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years) | 01          | Day 1         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years) | 01          | Day 2         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years) | 01          | Day 3         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years) | 01          | Day 4         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years) | 01          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years) | 01          | Day 7         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years) | 01          | Day 8         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR01<br>4 | 50 µg<br>(≥71 years)   | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years)   | 02          | Day 1         | MA          | 36.7       | None         | None    | Mild    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years)   | 02          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years)   | 02          | Day 3         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years)   | 02          | Day 4         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years)   | 02          | Day 5         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years)   | 02          | Day 6         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years)   | 02          | Day 7         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>4 | 50 µg<br>(≥71 years)   | 02          | Day 8         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 01          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|--------|
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.6       | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.2       | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.5       | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.2       | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.5       | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.6       | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | 37.9       | Moderate     | Moderate | None    | None       | None     | None   |
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.6       | None         | Mild     | None    | None       | None     | None   |
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36.3       | None         | Moderate | None    | None       | None     | None   |
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | 36.2       | None         | Mild     | None    | None       | None     | None   |
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | 36.4       | None         | Mild     | None    | None       | Mild     | None   |
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | 36.4       | None         | None     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR01<br>6 | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>7 | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years)   | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years)   | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years)   | 01          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years)   | 01          | Day 2         | MA          | 36.4       | None         | Mild    | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years)   | 01          | Day 3         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years)   | 01          | Day 4         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years)   | 01          | Day 5         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|---------------|----------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|--------|
| CV01VR01<br>8 | 50 µg<br>(≥71 years) | 01          | Day 6         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years) | 01          | Day 7         | MA          | 36.5       | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years) | 01          | Day 8         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years) | 02          | Day 1         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years) | 02          | Day 2         | MA          | 36.3       | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years) | 02          | Day 3         | MA          | 36.8       | None         | Moderate | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years) | 02          | Day 4         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years) | 02          | Day 5         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years) | 02          | Day 6         | MA          | 36.4       | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years) | 02          | Day 7         | MA          | 36.6       | None         | None     | None    | None       | None     | None   |
| CV01VR01<br>8 | 50 µg<br>(≥71 years) | 02          | Day 8         | MA          | 36.4       | None         | None     | None    | None       | None     | None   |
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 01          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 01          | Day 2         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 01          | Day 3         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 01          | Day 6         | MA          | 35.7       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 01          | Day 7         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 01          | Day 8         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 02          | Day 1         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 02          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 02          | Day 3         | MA          | 36.1       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 02          | Day 4         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 02          | Day 5         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 02          | Day 6         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 02          | Day 7         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>1 | 50 µg<br>(≥71 years) | 02          | Day 8         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years) | 01          | Day 1         | MA          | 36.7       | None         | Mild    | None    | None       | None     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years) | 01          | Day 2         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years) | 01          | Day 3         | MA          | 36.4       | None         | Mild    | None    | None       | None     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years) | 01          | Day 4         | MA          | 35.7       | None         | None    | None    | None       | Mild     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years) | 01          | Day 6         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years) | 01          | Day 7         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR02<br>3 | 50 µg<br>(≥71 years)   | 01          | Day 8         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years)   | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years)   | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years)   | 02          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years)   | 02          | Day 2         | MA          | 36.4       | None         | Mild    | None    | None       | None     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years)   | 02          | Day 3         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years)   | 02          | Day 4         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years)   | 02          | Day 5         | MA          | 36.3       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years)   | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years)   | 02          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>3 | 50 µg<br>(≥71 years)   | 02          | Day 8         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 01          | Day 1         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36         | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | 36.1       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>4 | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 01          | Day 1         | MA          | 36.9       | None         | Mild    | None    | None       | None     | Mild   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 01          | Day 2         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 01          | Day 3         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 01          | Day 4         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 01          | Day 5         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | 36.5       | None         | None    | None    | None       | None     | None   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue  | Myalgia | Arthralgia | Headache | Nausea |
|---------------|------------------------|-------------|---------------|-------------|------------|--------------|----------|---------|------------|----------|--------|
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | 36.7       | None         | Mild     | Mild    | Mild       | None     | None   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | 36.4       | None         | None     | Mild    | Mild       | None     | None   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | 36.6       | None         | None     | None    | None       | None     | None   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | 35.7       | None         | None     | None    | None       | None     | None   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | 36.7       | None         | None     | None    | None       | None     | None   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | 36.6       | None         | None     | None    | None       | None     | None   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | 36.2       | None         | None     | None    | None       | None     | None   |
| CV01VR02<br>8 | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | 36.5       | None         | None     | None    | None       | None     | None   |
| CV01VR03<br>0 | 50 µg<br>(≥71 years)   | 01          | Pre-Dose      | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01VR03<br>0 | 50 µg<br>(≥71 years)   | 01          | Post-Dose     | Clinic      | N/A        | None         | None     | None    | None       | None     | None   |
| CV01VR03<br>0 | 50 µg<br>(≥71 years)   | 01          | Day 1         | MA          | 37.2       | None         | Moderate | None    | None       | None     | None   |
| CV01VR03<br>0 | 50 µg<br>(≥71 years)   | 01          | Day 2         | MA          | 37.2       | None         | Mild     | None    | Mild       | None     | None   |
| CV01VR03<br>0 | 50 µg<br>(≥71 years)   | 01          | Day 3         | MA          | 36.6       | None         | Mild     | None    | Mild       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR03<br>0 | 50 µg<br>(≥71 years) | 01          | Day 4         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>0 | 50 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>0 | 50 µg<br>(≥71 years) | 01          | Day 6         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>0 | 50 µg<br>(≥71 years) | 01          | Day 7         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>0 | 50 µg<br>(≥71 years) | 01          | Day 8         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>0 | 50 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>0 | 50 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>0 | 50 µg<br>(≥71 years) | 02          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>0 | 50 µg<br>(≥71 years) | 02          | Day 2         | MA          | 36.7       | None         | Mild    | None    | None       | None     | None   |
| CV01VR03<br>0 | 50 µg<br>(≥71 years) | 02          | Day 3         | MA          | 36.4       | None         | Mild    | None    | None       | None     | None   |
| CV01VR03<br>0 | 50 µg<br>(≥71 years) | 02          | Day 4         | MA          | 36.9       | None         | Mild    | None    | None       | None     | None   |
| CV01VR03<br>0 | 50 µg<br>(≥71 years) | 02          | Day 5         | MA          | 36.5       | None         | Mild    | None    | None       | None     | None   |
| CV01VR03<br>0 | 50 µg<br>(≥71 years) | 02          | Day 6         | MA          | 37         | None         | Mild    | None    | None       | None     | None   |
| CV01VR03<br>0 | 50 µg<br>(≥71 years) | 02          | Day 7         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|------------|-------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR030  | 50 µg (≥71 years) | 02          | Day 8         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR035  | 50 µg (≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR035  | 50 µg (≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR035  | 50 µg (≥71 years) | 01          | Day 1         | MA          | 37.2       | None         | None    | None    | None       | None     | None   |
| CV01VR035  | 50 µg (≥71 years) | 01          | Day 2         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01VR035  | 50 µg (≥71 years) | 01          | Day 3         | MA          | 37.1       | None         | None    | None    | None       | None     | None   |
| CV01VR035  | 50 µg (≥71 years) | 01          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR035  | 50 µg (≥71 years) | 01          | Day 5         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR035  | 50 µg (≥71 years) | 01          | Day 6         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR035  | 50 µg (≥71 years) | 01          | Day 7         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR035  | 50 µg (≥71 years) | 01          | Day 8         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01VR035  | 50 µg (≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR035  | 50 µg (≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR035  | 50 µg (≥71 years) | 02          | Day 1         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR03<br>5 | 50 µg<br>(≥71 years) | 02          | Day 2         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>5 | 50 µg<br>(≥71 years) | 02          | Day 3         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>5 | 50 µg<br>(≥71 years) | 02          | Day 4         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>5 | 50 µg<br>(≥71 years) | 02          | Day 5         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>5 | 50 µg<br>(≥71 years) | 02          | Day 6         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>5 | 50 µg<br>(≥71 years) | 02          | Day 7         | MA          | 37         | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>5 | 50 µg<br>(≥71 years) | 02          | Day 8         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 01          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 01          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 01          | Day 1         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 01          | Day 2         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 01          | Day 3         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 01          | Day 4         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 01          | Day 5         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID    | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---------------|----------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 01          | Day 6         | MA          | 36.2       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 01          | Day 7         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 01          | Day 8         | MA          | 36.9       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 02          | Pre-Dose      | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 02          | Post-Dose     | Clinic      | N/A        | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 02          | Day 1         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 02          | Day 2         | MA          | 37.6       | None         | Mild    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 02          | Day 3         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 02          | Day 4         | MA          | 36.4       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 02          | Day 5         | MA          | 36.8       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 02          | Day 6         | MA          | 36.7       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 02          | Day 7         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |
| CV01VR03<br>7 | 50 µg<br>(≥71 years) | 02          | Day 8         | MA          | 36.6       | None         | None    | None    | None       | None     | None   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C1 (continued)**  
**Solicited Systemic Events**

| Subject ID  | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Fever (°C) | Feverishness | Fatigue | Myalgia | Arthralgia | Headache | Nausea |
|---|-------------------|-------------|---------------|-------------|------------|--------------|---------|---------|------------|----------|--------|
| <p>*MA = Data reported by subject on the Memory Aid and reviewed by clinic staff and reported in Solicited Events eCRF.<br/> Clinic = Data collected by clinic staff during physical exam or symptom assessment (treatment administration record, in-clinic assessment, etc.)<br/> See <a href="#">Appendix D</a> for listing of attributions for systemic events contributing toward halting criteria.</p> |                   |             |               |             |            |              |         |         |            |          |        |

**APPENDIX C2:  
Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM003  | 250 µg (18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM003  | 250 µg (18-55 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM003  | 250 µg (18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM003  | 250 µg (18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM003  | 250 µg (18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM003  | 250 µg (18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM003  | 250 µg (18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM003  | 250 µg (18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM003  | 250 µg (18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM003  | 250 µg (18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM003  | 250 µg (18-55 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM003  | 250 µg (18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM003  | 250 µg (18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM003  | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM003  | 250 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM003  | 250 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM003  | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM003  | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM004  | 100 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM004  | 100 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM004  | 100 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM004  | 100 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM004  | 100 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM004  | 100 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM004  | 100 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM004  | 100 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM004  | 100 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM004  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM004  | 100 µg (18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM004  | 100 µg (18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM004  | 100 µg (18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM004  | 100 µg (18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM004  | 100 µg (18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM004  | 100 µg (18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM004  | 100 µg (18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM004  | 100 µg (18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM005  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM005  | 100 µg (18-55 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM005  | 100 µg (18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM005  | 100 µg (18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM005  | 100 µg (18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM005  | 100 µg (18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM005  | 100 µg (18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM005  | 100 µg (18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM005  | 100 µg (18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM005  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM005  | 100 µg (18-55 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM005  | 100 µg (18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM005  | 100 µg (18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM005  | 100 µg (18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM005  | 100 µg (18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM005  | 100 µg (18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM005  | 100 µg (18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM005  | 100 µg (18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM007  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM007  | 100 µg (18-55 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM007  | 100 µg (18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM007  | 100 µg (18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM007  | 100 µg (18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM007  | 100 µg (18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM007  | 100 µg (18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM007  | 100 µg (18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM007  | 100 µg (18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM007  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM007  | 100 µg (18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM007  | 100 µg (18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM007  | 100 µg (18-55 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM007  | 100 µg (18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM007  | 100 µg (18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM007  | 100 µg (18-55 years) | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM007  | 100 µg (18-55 years) | 02          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM007  | 100 µg (18-55 years) | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM009  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01EM009  | 100 µg (18-55 years) | 01          | Day 1         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01EM009  | 100 µg (18-55 years) | 01          | Day 2         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01EM009  | 100 µg (18-55 years) | 01          | Day 3         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM009  | 100 µg (18-55 years) | 01          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM009  | 100 µg (18-55 years) | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM009  | 100 µg (18-55 years) | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM009  | 100 µg (18-55 years) | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM009  | 100 µg (18-55 years) | 01          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM009  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01EM009  | 100 µg (18-55 years) | 02          | Day 1         | MA          | Moderate | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM009  | 100 µg (18-55 years) | 02          | Day 2         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01EM009  | 100 µg (18-55 years) | 02          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01EM009  | 100 µg (18-55 years) | 02          | Day 4         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01EM009  | 100 µg (18-55 years) | 02          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM009  | 100 µg (18-55 years) | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM009  | 100 µg (18-55 years) | 02          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM009  | 100 µg (18-55 years) | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM010  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | None     | None             | Mild                | 0                                 | 1                        |
| CV01EM010  | 100 µg (18-55 years) | 01          | Day 1         | MA          | Mild     | None             | Mild                | 0                                 | 2                        |
| CV01EM010  | 100 µg (18-55 years) | 01          | Day 2         | MA          | Mild     | None             | Mild                | 0                                 | 2                        |
| CV01EM010  | 100 µg (18-55 years) | 01          | Day 3         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM010  | 100 µg (18-55 years) | 01          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM010  | 100 µg (18-55 years) | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM010  | 100 µg (18-55 years) | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM010  | 100 µg (18-55 years) | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM010  | 100 µg (18-55 years) | 01          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM010  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01EM010  | 100 µg (18-55 years) | 02          | Day 1         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01EM010  | 100 µg (18-55 years) | 02          | Day 2         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01EM010  | 100 µg (18-55 years) | 02          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01EM010  | 100 µg (18-55 years) | 02          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM010  | 100 µg (18-55 years) | 02          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM010  | 100 µg (18-55 years) | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM010  | 100 µg (18-55 years) | 02          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM010  | 100 µg (18-55 years) | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM012  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01EM012  | 100 µg (18-55 years) | 01          | Day 1         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM012  | 100 µg (18-55 years) | 01          | Day 2         | MA          | Mild     | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM012  | 100 µg (18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM012  | 100 µg (18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM012  | 100 µg (18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM012  | 100 µg (18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM012  | 100 µg (18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM012  | 100 µg (18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM012  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM012  | 100 µg (18-55 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM012  | 100 µg (18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM012  | 100 µg (18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM012  | 100 µg (18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM012  | 100 µg (18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM012  | 100 µg (18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM012  | 100 µg (18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM012  | 100 µg<br>(18-55 years) | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | Mild     | None             | None                | 0                                 | 0                        |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | Moderate | None             | Moderate            | 0                                 | 75<br>(Moderate)         |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild     | None             | Moderate            | 0                                 | 78<br>(Moderate)         |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | None     | None             | Mild                | 0                                 | 36 (Mild)                |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | None     | None             | Mild                | 0                                 | 26 (Mild)                |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01EM016  | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM016  | 250 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01EM016  | 250 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild     | None             | Moderate            | 0                                 | 65<br>(Moderate)         |
| CV01EM016  | 250 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild     | None             | Moderate            | 0                                 | 76<br>(Moderate)         |
| CV01EM016  | 250 µg<br>(18-55 years) | 02          | Day 3         | MA          | Mild     | None             | Mild                | 0                                 | 23                       |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM016  | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM016  | 250 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM016  | 250 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM016  | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM016  | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM020  | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM020  | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM020  | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM020  | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM020  | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM020  | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM020  | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM020  | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM020  | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM020  | 250 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01EM020  | 250 µg<br>(18-55 years) | 02          | Day 1         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01EM020  | 250 µg<br>(18-55 years) | 02          | Day 2         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01EM020  | 250 µg<br>(18-55 years) | 02          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01EM020  | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01EM020  | 250 µg<br>(18-55 years) | 02          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM020  | 250 µg<br>(18-55 years) | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM020  | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM020  | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM023  | 100 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01EM023  | 100 µg<br>(56-70 years) | 01          | Day 1         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM023  | 100 µg<br>(56-70 years) | 01          | Day 2         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01EM023  | 100 µg<br>(56-70 years) | 01          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01EM023  | 100 µg<br>(56-70 years) | 01          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM023  | 100 µg (56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM023  | 100 µg (56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM023  | 100 µg (56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM023  | 100 µg (56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM023  | 100 µg (56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM023  | 100 µg (56-70 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM023  | 100 µg (56-70 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM023  | 100 µg (56-70 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM023  | 100 µg (56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM023  | 100 µg (56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM023  | 100 µg (56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM023  | 100 µg (56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM023  | 100 µg (56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM024  | 100 µg (56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM024  | 100 µg<br>(56-70 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM024  | 100 µg<br>(56-70 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM024  | 100 µg<br>(56-70 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM024  | 100 µg<br>(56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM024  | 100 µg<br>(56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM024  | 100 µg<br>(56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM024  | 100 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM024  | 100 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM024  | 100 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM024  | 100 µg<br>(56-70 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM024  | 100 µg<br>(56-70 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM024  | 100 µg<br>(56-70 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM024  | 100 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM024  | 100 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM024  | 100 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM024  | 100 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM024  | 100 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM025  | 25 µg<br>(56-70 years)  | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM025  | 25 µg<br>(56-70 years)  | 01          | Day 1         | MA          | Mild | None             | Mild                | 0                                 | 35 (Mild)                |
| CV01EM025  | 25 µg<br>(56-70 years)  | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM025  | 25 µg<br>(56-70 years)  | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM025  | 25 µg<br>(56-70 years)  | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM025  | 25 µg<br>(56-70 years)  | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM025  | 25 µg<br>(56-70 years)  | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM025  | 25 µg<br>(56-70 years)  | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM025  | 25 µg<br>(56-70 years)  | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM025  | 25 µg<br>(56-70 years)  | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM025  | 25 µg<br>(56-70 years)  | 02          | Day 1         | MA          | Mild | None             | Mild                | 0                                 | 20                       |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM025  | 25 µg<br>(56-70 years) | 02          | Day 2         | MA          | Mild | None             | Mild                | 0                                 | 15                       |
| CV01EM025  | 25 µg<br>(56-70 years) | 02          | Day 3         | MA          | Mild | None             | Mild                | 0                                 | 10                       |
| CV01EM025  | 25 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM025  | 25 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM025  | 25 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM025  | 25 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM025  | 25 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM027  | 25 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM027  | 25 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM027  | 25 µg<br>(56-70 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM027  | 25 µg<br>(56-70 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM027  | 25 µg<br>(56-70 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM027  | 25 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM027  | 25 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM027  | 25 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM027  | 25 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM027  | 25 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM029  | 25 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM029  | 25 µg<br>(56-70 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM029  | 25 µg<br>(56-70 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM029  | 25 µg<br>(56-70 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM029  | 25 µg<br>(56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM029  | 25 µg<br>(56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM029  | 25 µg<br>(56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM029  | 25 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM029  | 25 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM029  | 25 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Day 1         | MA          | None | Mild             | None                | 1                                 | 0                        |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Day 2         | MA          | None | Mild             | None                | 1                                 | 0                        |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Day 3         | MA          | None | Mild             | None                | 3                                 | 0                        |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Day 4         | MA          | None | Mild             | None                | 3                                 | 0                        |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Day 5         | MA          | None | Mild             | None                | 3                                 | 0                        |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Day 6         | MA          | None | Mild             | None                | 2                                 | 0                        |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | Mild             | None                | 2                                 | 0                        |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | Mild             | None                | 2                                 | 0                        |
| CV01EM030  | 25 µg<br>(56-70 years) | 01          | Day 10        | MA          | .    | Mild             | .                   | 2                                 | .                        |
| CV01EM030  | 25 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM030  | 25 µg<br>(56-70 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM030  | 25 µg<br>(56-70 years) | 02          | Day 2         | MA          | Mild | Mild             | None                | 1                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM030  | 25 µg<br>(56-70 years)  | 02          | Day 3         | MA          | Mild | Mild             | None                | 1                                 | 0                        |
| CV01EM030  | 25 µg<br>(56-70 years)  | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM030  | 25 µg<br>(56-70 years)  | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM030  | 25 µg<br>(56-70 years)  | 02          | Day 6         | MA          | Mild | Mild             | Mild                | 70<br>(Moderate)                  | 70<br>(Moderate)         |
| CV01EM030  | 25 µg<br>(56-70 years)  | 02          | Day 7         | MA          | Mild | Mild             | Mild                | 70<br>(Moderate)                  | 70<br>(Moderate)         |
| CV01EM030  | 25 µg<br>(56-70 years)  | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM032  | 100 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 1                        |
| CV01EM032  | 100 µg<br>(56-70 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM032  | 100 µg<br>(56-70 years) | 01          | Day 2         | MA          | Mild | None             | Mild                | 0                                 | 10                       |
| CV01EM032  | 100 µg<br>(56-70 years) | 01          | Day 3         | MA          | Mild | None             | Mild                | 0                                 | 8                        |
| CV01EM032  | 100 µg<br>(56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM032  | 100 µg<br>(56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM032  | 100 µg<br>(56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM032  | 100 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM032  | 100 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM032  | 100 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM032  | 100 µg<br>(56-70 years) | 02          | Day 1         | MA          | Mild | None             | Mild                | 0                                 | 3                        |
| CV01EM032  | 100 µg<br>(56-70 years) | 02          | Day 2         | MA          | Mild | None             | Mild                | 0                                 | 2                        |
| CV01EM032  | 100 µg<br>(56-70 years) | 02          | Day 3         | MA          | None | None             | Mild                | 0                                 | 2                        |
| CV01EM032  | 100 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | Mild                | 0                                 | 2                        |
| CV01EM032  | 100 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM032  | 100 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM032  | 100 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM032  | 100 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM033  | 100 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 3                                 | 0                        |
| CV01EM033  | 100 µg<br>(56-70 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM033  | 100 µg<br>(56-70 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM033  | 100 µg<br>(56-70 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM033  | 100 µg<br>(56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM033  | 100 µg<br>(56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM033  | 100 µg<br>(56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM033  | 100 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM033  | 100 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM033  | 100 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | Mild             | None                | 2                                 | 0                        |
| CV01EM033  | 100 µg<br>(56-70 years) | 02          | Day 1         | MA          | None | Mild             | None                | 2                                 | 0                        |
| CV01EM033  | 100 µg<br>(56-70 years) | 02          | Day 2         | MA          | Mild | Mild             | None                | 3                                 | 0                        |
| CV01EM033  | 100 µg<br>(56-70 years) | 02          | Day 3         | MA          | Mild | Mild             | None                | 3                                 | 0                        |
| CV01EM033  | 100 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | Mild             | None                | 3                                 | 0                        |
| CV01EM033  | 100 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | Mild             | None                | 2                                 | 0                        |
| CV01EM033  | 100 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM033  | 100 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM033  | 100 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM039  | 100 µg (56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM039  | 100 µg (56-70 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM039  | 100 µg (56-70 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM039  | 100 µg (56-70 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM039  | 100 µg (56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM039  | 100 µg (56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM039  | 100 µg (56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM039  | 100 µg (56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM039  | 100 µg (56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM039  | 100 µg (56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM039  | 100 µg (56-70 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM039  | 100 µg (56-70 years) | 02          | Day 2         | MA          | Mild | Mild             | None                | 25 (Mild)                         | 0                        |
| CV01EM039  | 100 µg (56-70 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM039  | 100 µg (56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM039  | 100 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM039  | 100 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM039  | 100 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM039  | 100 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM041  | 25 µg<br>(56-70 years)  | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM041  | 25 µg<br>(56-70 years)  | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM041  | 25 µg<br>(56-70 years)  | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM041  | 25 µg<br>(56-70 years)  | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM041  | 25 µg<br>(56-70 years)  | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM041  | 25 µg<br>(56-70 years)  | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM041  | 25 µg<br>(56-70 years)  | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM041  | 25 µg<br>(56-70 years)  | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM041  | 25 µg<br>(56-70 years)  | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM041  | 25 µg<br>(56-70 years)  | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM041  | 25 µg<br>(56-70 years)  | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM041  | 25 µg<br>(56-70 years)  | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM041  | 25 µg<br>(56-70 years)  | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM041  | 25 µg<br>(56-70 years)  | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM041  | 25 µg<br>(56-70 years)  | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM041  | 25 µg<br>(56-70 years)  | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM041  | 25 µg<br>(56-70 years)  | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM041  | 25 µg<br>(56-70 years)  | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM045  | 100 µg<br>(56-70 years) | 01          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM049  | 50 µg<br>(18-55 years)  | 01          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01EM049  | 50 µg<br>(18-55 years)  | 01          | Day 1         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01EM049  | 50 µg<br>(18-55 years)  | 01          | Day 2         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01EM049  | 50 µg<br>(18-55 years)  | 01          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01EM049  | 50 µg<br>(18-55 years)  | 01          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM049  | 50 µg<br>(18-55 years)  | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM049  | 50 µg<br>(18-55 years)  | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM049  | 50 µg<br>(18-55 years)  | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM049  | 50 µg<br>(18-55 years)  | 01          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM049  | 50 µg<br>(18-55 years)  | 02          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01EM049  | 50 µg<br>(18-55 years)  | 02          | Day 1         | MA          | Mild     | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM049  | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM049  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM049  | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM049  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM049  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM049  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM049  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM051  | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01EM051  | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM051  | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM051  | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM051  | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM051  | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM051  | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM051  | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM051  | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM051  | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01EM051  | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM051  | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM051  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM051  | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM051  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM051  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM051  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM051  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM053  | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01EM053  | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01EM053  | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | Moderate | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM053  | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01EM053  | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM053  | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM053  | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM053  | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM053  | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM053  | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01EM053  | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01EM053  | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01EM053  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01EM053  | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM053  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM053  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01EM053  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM053  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | Mild | None             | None                | 0                                 | 0                        |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM054  | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM054  | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | Mild             | None                | 2                                 | 0                        |
| CV01EM054  | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | None | Mild             | None                | 1                                 | 0                        |
| CV01EM054  | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM054  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01EM054  | 50 µg<br>(18-55 years)  | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM054  | 50 µg<br>(18-55 years)  | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM054  | 50 µg<br>(18-55 years)  | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM054  | 50 µg<br>(18-55 years)  | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01EM054  | 50 µg<br>(18-55 years)  | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC001  | 100 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC001  | 100 µg<br>(18-55 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC001  | 100 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC001  | 100 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC001  | 100 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC001  | 100 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC001  | 100 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC001  | 100 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC001  | 100 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC001  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC001  | 100 µg (18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC001  | 100 µg (18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC001  | 100 µg (18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC001  | 100 µg (18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC001  | 100 µg (18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC001  | 100 µg (18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC001  | 100 µg (18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC001  | 100 µg (18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC003  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | Mild | None             | None                | 0                                 | 0                        |
| CV01HC003  | 100 µg (18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC003  | 100 µg (18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC003  | 100 µg (18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC003  | 100 µg (18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC003  | 100 µg (18-55 years) | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC003  | 100 µg (18-55 years) | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC003  | 100 µg (18-55 years) | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC003  | 100 µg (18-55 years) | 01          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC003  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01HC003  | 100 µg (18-55 years) | 02          | Day 1         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01HC003  | 100 µg (18-55 years) | 02          | Day 2         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01HC003  | 100 µg (18-55 years) | 02          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01HC003  | 100 µg (18-55 years) | 02          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC003  | 100 µg (18-55 years) | 02          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC003  | 100 µg (18-55 years) | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC003  | 100 µg (18-55 years) | 02          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC003  | 100 µg (18-55 years) | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC004  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC004  | 100 µg (18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC004  | 100 µg (18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC004  | 100 µg (18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC004  | 100 µg (18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC004  | 100 µg (18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC004  | 100 µg (18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC004  | 100 µg (18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC004  | 100 µg (18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC004  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | Mild | None             | None                | 0                                 | 0                        |
| CV01HC004  | 100 µg (18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC004  | 100 µg (18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC004  | 100 µg (18-55 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC004  | 100 µg (18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC004  | 100 µg (18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC004  | 100 µg (18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC004  | 100 µg (18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC004  | 100 µg (18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC007  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC007  | 100 µg (18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC007  | 100 µg (18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC007  | 100 µg (18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC007  | 100 µg (18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC007  | 100 µg (18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC007  | 100 µg (18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC007  | 100 µg (18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC007  | 100 µg (18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC007  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC007  | 100 µg (18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC007  | 100 µg (18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC007  | 100 µg (18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC007  | 100 µg (18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC007  | 100 µg (18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC007  | 100 µg (18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC007  | 100 µg (18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC007  | 100 µg (18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC008  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC008  | 100 µg (18-55 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC008  | 100 µg (18-55 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC008  | 100 µg (18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC008  | 100 µg (18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC008  | 100 µg (18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC008  | 100 µg (18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC008  | 100 µg (18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC008  | 100 µg (18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC008  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC008  | 100 µg (18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC008  | 100 µg (18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC008  | 100 µg (18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC008  | 100 µg (18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC008  | 100 µg (18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC008  | 100 µg (18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC008  | 100 µg (18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC008  | 100 µg (18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC012  | 250 µg (18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC012  | 250 µg (18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC012  | 250 µg (18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC012  | 250 µg (18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC012  | 250 µg (18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC012  | 250 µg (18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC012  | 250 µg (18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC012  | 250 µg (18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC012  | 250 µg (18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC012  | 250 µg (18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC012  | 250 µg (18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC012  | 250 µg (18-55 years) | 02          | Day 2         | MA          | None | Mild             | None                | 65 (Moderate)                     | 0                        |
| CV01HC012  | 250 µg (18-55 years) | 02          | Day 3         | MA          | Mild | Mild             | None                | 65 (Moderate)                     | 0                        |
| CV01HC012  | 250 µg (18-55 years) | 02          | Day 4         | MA          | Mild | Mild             | None                | 40 (Mild)                         | 0                        |
| CV01HC012  | 250 µg (18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC012  | 250 µg (18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC012  | 250 µg (18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC012  | 250 µg (18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC013  | 250 µg (18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC013  | 250 µg (18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC013  | 250 µg (18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC013  | 250 µg (18-55 years) | 01          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC013  | 250 µg (18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC013  | 250 µg (18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC013  | 250 µg (18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC013  | 250 µg (18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC013  | 250 µg (18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC013  | 250 µg (18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC013  | 250 µg (18-55 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC013  | 250 µg (18-55 years) | 02          | Day 2         | MA          | Mild | Mild             | None                | 40 (Mild)                         | 0                        |
| CV01HC013  | 250 µg (18-55 years) | 02          | Day 3         | MA          | Mild | Mild             | None                | 50 (Moderate)                     | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC013  | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | Mild             | None                | 25 (Mild)                         | 0                        |
| CV01HC013  | 250 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC013  | 250 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC013  | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC013  | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC016  | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC016  | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC016  | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC016  | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC016  | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC016  | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC016  | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC016  | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC016  | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC016  | 250 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC016  | 250 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC016  | 250 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC016  | 250 µg<br>(18-55 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC016  | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC016  | 250 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC016  | 250 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC016  | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC016  | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC026  | 25 µg<br>(56-70 years)  | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC026  | 25 µg<br>(56-70 years)  | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC026  | 25 µg<br>(56-70 years)  | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC026  | 25 µg<br>(56-70 years)  | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC026  | 25 µg<br>(56-70 years)  | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC026  | 25 µg<br>(56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC026  | 25 µg<br>(56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC026  | 25 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC026  | 25 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC026  | 25 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC026  | 25 µg<br>(56-70 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC026  | 25 µg<br>(56-70 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC026  | 25 µg<br>(56-70 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC026  | 25 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC026  | 25 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC026  | 25 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC026  | 25 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC026  | 25 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC027  | 25 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC027  | 25 µg<br>(56-70 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC027  | 25 µg<br>(56-70 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC027  | 25 µg<br>(56-70 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC027  | 25 µg<br>(56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC027  | 25 µg<br>(56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC027  | 25 µg<br>(56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC027  | 25 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC027  | 25 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC027  | 25 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC027  | 25 µg<br>(56-70 years) | 02          | Day 1         | MA          | Mild | None             | Mild                | 0                                 | 50<br>(Moderate)         |
| CV01HC027  | 25 µg<br>(56-70 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC027  | 25 µg<br>(56-70 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC027  | 25 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC027  | 25 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC027  | 25 µg<br>(56-70 years)  | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC027  | 25 µg<br>(56-70 years)  | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC027  | 25 µg<br>(56-70 years)  | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC031  | 100 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC031  | 100 µg<br>(56-70 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC031  | 100 µg<br>(56-70 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC031  | 100 µg<br>(56-70 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC031  | 100 µg<br>(56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC031  | 100 µg<br>(56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC031  | 100 µg<br>(56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC031  | 100 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC031  | 100 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC031  | 100 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC031  | 100 µg<br>(56-70 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC031  | 100 µg<br>(56-70 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC031  | 100 µg<br>(56-70 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC031  | 100 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC031  | 100 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC031  | 100 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC031  | 100 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC031  | 100 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC032  | 25 µg<br>(56-70 years)  | 01          | Post-Dose     | Clinic      | None | None             | Mild                | 0                                 | 15                       |
| CV01HC032  | 25 µg<br>(56-70 years)  | 01          | Day 1         | MA          | None | None             | Mild                | 0                                 | 20                       |
| CV01HC032  | 25 µg<br>(56-70 years)  | 01          | Day 2         | MA          | None | None             | Mild                | 0                                 | 5                        |
| CV01HC032  | 25 µg<br>(56-70 years)  | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC032  | 25 µg<br>(56-70 years)  | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC032  | 25 µg<br>(56-70 years)  | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC032  | 25 µg<br>(56-70 years)  | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC032  | 25 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC032  | 25 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC032  | 25 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC032  | 25 µg<br>(56-70 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC032  | 25 µg<br>(56-70 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC032  | 25 µg<br>(56-70 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC032  | 25 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC032  | 25 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC032  | 25 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC032  | 25 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC032  | 25 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC033  | 25 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC033  | 25 µg<br>(56-70 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC033  | 25 µg<br>(56-70 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC033  | 25 µg<br>(56-70 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC033  | 25 µg<br>(56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC033  | 25 µg<br>(56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC033  | 25 µg<br>(56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC033  | 25 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC033  | 25 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC033  | 25 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | Mild                | 0                                 | 1                        |
| CV01HC033  | 25 µg<br>(56-70 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC033  | 25 µg<br>(56-70 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC033  | 25 µg<br>(56-70 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC033  | 25 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC033  | 25 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC033  | 25 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC033  | 25 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC033  | 25 µg<br>(56-70 years)  | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC034  | 100 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | Mild     | Mild             | Mild                | 2                                 | 3                        |
| CV01HC034  | 100 µg<br>(56-70 years) | 01          | Day 1         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01HC034  | 100 µg<br>(56-70 years) | 01          | Day 2         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01HC034  | 100 µg<br>(56-70 years) | 01          | Day 3         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC034  | 100 µg<br>(56-70 years) | 01          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC034  | 100 µg<br>(56-70 years) | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC034  | 100 µg<br>(56-70 years) | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC034  | 100 µg<br>(56-70 years) | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC034  | 100 µg<br>(56-70 years) | 01          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC034  | 100 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01HC034  | 100 µg<br>(56-70 years) | 02          | Day 1         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC034  | 100 µg<br>(56-70 years) | 02          | Day 2         | MA          | Moderate | None             | Moderate            | 0                                 | 50<br>(Moderate)         |
| CV01HC034  | 100 µg<br>(56-70 years) | 02          | Day 3         | MA          | Mild     | None             | Mild                | 0                                 | 50<br>(Moderate)         |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC034  | 100 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC034  | 100 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC034  | 100 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC034  | 100 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC034  | 100 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC035  | 25 µg<br>(56-70 years)  | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC035  | 25 µg<br>(56-70 years)  | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC035  | 25 µg<br>(56-70 years)  | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC035  | 25 µg<br>(56-70 years)  | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC035  | 25 µg<br>(56-70 years)  | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC035  | 25 µg<br>(56-70 years)  | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC035  | 25 µg<br>(56-70 years)  | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC035  | 25 µg<br>(56-70 years)  | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC035  | 25 µg<br>(56-70 years)  | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC035  | 25 µg<br>(56-70 years)  | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC035  | 25 µg<br>(56-70 years)  | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC035  | 25 µg<br>(56-70 years)  | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC035  | 25 µg<br>(56-70 years)  | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC035  | 25 µg<br>(56-70 years)  | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC035  | 25 µg<br>(56-70 years)  | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC035  | 25 µg<br>(56-70 years)  | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC035  | 25 µg<br>(56-70 years)  | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC035  | 25 µg<br>(56-70 years)  | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC037  | 100 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC037  | 100 µg<br>(56-70 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC037  | 100 µg<br>(56-70 years) | 01          | Day 2         | MA          | Mild | None             | Mild                | 0                                 | 3                        |
| CV01HC037  | 100 µg<br>(56-70 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC037  | 100 µg<br>(56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC037  | 100 µg (56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC037  | 100 µg (56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC037  | 100 µg (56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC037  | 100 µg (56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC037  | 100 µg (56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC037  | 100 µg (56-70 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC037  | 100 µg (56-70 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC037  | 100 µg (56-70 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC037  | 100 µg (56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC037  | 100 µg (56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC037  | 100 µg (56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC037  | 100 µg (56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC037  | 100 µg (56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC038  | 100 µg (56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC038  | 100 µg<br>(56-70 years) | 01          | Day 1         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01HC038  | 100 µg<br>(56-70 years) | 01          | Day 2         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01HC038  | 100 µg<br>(56-70 years) | 01          | Day 3         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC038  | 100 µg<br>(56-70 years) | 01          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC038  | 100 µg<br>(56-70 years) | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC038  | 100 µg<br>(56-70 years) | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC038  | 100 µg<br>(56-70 years) | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC038  | 100 µg<br>(56-70 years) | 01          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC038  | 100 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01HC038  | 100 µg<br>(56-70 years) | 02          | Day 1         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01HC038  | 100 µg<br>(56-70 years) | 02          | Day 2         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01HC038  | 100 µg<br>(56-70 years) | 02          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01HC038  | 100 µg<br>(56-70 years) | 02          | Day 4         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01HC038  | 100 µg<br>(56-70 years) | 02          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC038  | 100 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC038  | 100 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC038  | 100 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC048  | 50 µg<br>(18-55 years)  | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC048  | 50 µg<br>(18-55 years)  | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC048  | 50 µg<br>(18-55 years)  | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC048  | 50 µg<br>(18-55 years)  | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC048  | 50 µg<br>(18-55 years)  | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC048  | 50 µg<br>(18-55 years)  | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC048  | 50 µg<br>(18-55 years)  | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC048  | 50 µg<br>(18-55 years)  | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC048  | 50 µg<br>(18-55 years)  | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC048  | 50 µg<br>(18-55 years)  | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC048  | 50 µg<br>(18-55 years)  | 02          | Day 1         | MA          | Mild | Mild             | None                | 1                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC048  | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC048  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC048  | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC048  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC048  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC048  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC048  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | Mild             | Mild                | 2                                 | 2                        |
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | Mild             | None                | 1                                 | 0                        |
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC050  | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | Moderate | Mild             | None                | 2                                 | 0                        |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC050  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC051  | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01HC051  | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild     | None             | Mild                | 0                                 | 50<br>(Moderate)         |
| CV01HC051  | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild     | None             | Mild                | 0                                 | 50<br>(Moderate)         |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC051  | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | Mild     | None             | Mild                | 0                                 | 50<br>(Moderate)         |
| CV01HC051  | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | None     | None             | Mild                | 0                                 | 25 (Mild)                |
| CV01HC051  | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC051  | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC051  | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC051  | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC051  | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01HC051  | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01HC051  | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC051  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC051  | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC051  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC051  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01HC051  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC051  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC054  | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC054  | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC054  | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC054  | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC054  | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC054  | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC054  | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC054  | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC054  | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01HC054  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP001  | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP001  | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP005  | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP005  | 25 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP005  | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP005  | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP005  | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP005  | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP005  | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP005  | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP005  | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP005  | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP006  | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP006  | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP006  | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP006  | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP006  | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP006  | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP006  | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP006  | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP006  | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP006  | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP007  | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP007  | 25 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP007  | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP007  | 25 µg<br>(18-55 years)  | 02          | Day 2         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP007  | 25 µg<br>(18-55 years)  | 02          | Day 3         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP007  | 25 µg<br>(18-55 years)  | 02          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP007  | 25 µg<br>(18-55 years)  | 02          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP007  | 25 µg<br>(18-55 years)  | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP007  | 25 µg<br>(18-55 years)  | 02          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP007  | 25 µg<br>(18-55 years)  | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP008  | 100 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01KP008  | 100 µg<br>(18-55 years) | 01          | Day 1         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01KP008  | 100 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP008  | 100 µg<br>(18-55 years) | 01          | Day 3         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP008  | 100 µg<br>(18-55 years) | 01          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP008  | 100 µg<br>(18-55 years) | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP008  | 100 µg<br>(18-55 years) | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP008  | 100 µg (18-55 years) | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP008  | 100 µg (18-55 years) | 01          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP008  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01KP008  | 100 µg (18-55 years) | 02          | Day 1         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01KP008  | 100 µg (18-55 years) | 02          | Day 2         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01KP008  | 100 µg (18-55 years) | 02          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP008  | 100 µg (18-55 years) | 02          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP008  | 100 µg (18-55 years) | 02          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP008  | 100 µg (18-55 years) | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP008  | 100 µg (18-55 years) | 02          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP008  | 100 µg (18-55 years) | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP009  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01KP009  | 100 µg (18-55 years) | 01          | Day 1         | MA          | Mild     | None             | Mild                | 0                                 | 2                        |
| CV01KP009  | 100 µg (18-55 years) | 01          | Day 2         | MA          | Moderate | Mild             | Mild                | 5                                 | 30 (Mild)                |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP009  | 100 µg (18-55 years) | 01          | Day 3         | MA          | None | Mild             | Mild                | 60 (Moderate)                     | 45 (Mild)                |
| CV01KP009  | 100 µg (18-55 years) | 01          | Day 4         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP009  | 100 µg (18-55 years) | 01          | Day 5         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP009  | 100 µg (18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP009  | 100 µg (18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP009  | 100 µg (18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP009  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP009  | 100 µg (18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP009  | 100 µg (18-55 years) | 02          | Day 2         | MA          | Mild | Mild             | None                | 35 (Mild)                         | 0                        |
| CV01KP009  | 100 µg (18-55 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP009  | 100 µg (18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP009  | 100 µg (18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP009  | 100 µg (18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP009  | 100 µg (18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP009  | 100 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP010  | 25 µg<br>(18-55 years)  | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP010  | 25 µg<br>(18-55 years)  | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP010  | 25 µg<br>(18-55 years)  | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP010  | 25 µg<br>(18-55 years)  | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP010  | 25 µg<br>(18-55 years)  | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP010  | 25 µg<br>(18-55 years)  | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP010  | 25 µg<br>(18-55 years)  | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP010  | 25 µg<br>(18-55 years)  | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP010  | 25 µg<br>(18-55 years)  | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP010  | 25 µg<br>(18-55 years)  | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP010  | 25 µg<br>(18-55 years)  | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP010  | 25 µg<br>(18-55 years)  | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP010  | 25 µg<br>(18-55 years)  | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP010  | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP010  | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP010  | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP010  | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP010  | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP011  | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP011  | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP011  | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP011  | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP011  | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP011  | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP011  | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP011  | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP011  | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP011  | 25 µg<br>(18-55 years)  | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP011  | 25 µg<br>(18-55 years)  | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP011  | 25 µg<br>(18-55 years)  | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP011  | 25 µg<br>(18-55 years)  | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP011  | 25 µg<br>(18-55 years)  | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP011  | 25 µg<br>(18-55 years)  | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP011  | 25 µg<br>(18-55 years)  | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP011  | 25 µg<br>(18-55 years)  | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP011  | 25 µg<br>(18-55 years)  | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP012  | 100 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP012  | 100 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP012  | 100 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP012  | 100 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP012  | 100 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP012  | 100 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP012  | 100 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP012  | 100 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP012  | 100 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | Mild             | Mild                | 40 (Mild)                         | 40 (Mild)                |
| CV01KP012  | 100 µg<br>(18-55 years) | 01          | Day 12        | MA          | .    | Mild             | Mild                | 110<br>(Severe)                   | 40 (Mild)                |
| CV01KP012  | 100 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP012  | 100 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild | None             | Mild                | 0                                 | 50<br>(Moderate)         |
| CV01KP012  | 100 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | Mild             | Mild                | 80<br>(Moderate)                  | 80<br>(Moderate)         |
| CV01KP012  | 100 µg<br>(18-55 years) | 02          | Day 3         | MA          | Mild | Mild             | Mild                | 115<br>(Severe)                   | 90<br>(Moderate)         |
| CV01KP012  | 100 µg<br>(18-55 years) | 02          | Day 4         | MA          | Mild | Mild             | Mild                | 80<br>(Moderate)                  | 80<br>(Moderate)         |
| CV01KP012  | 100 µg<br>(18-55 years) | 02          | Day 5         | MA          | Mild | Mild             | None                | 60<br>(Moderate)                  | 0                        |
| CV01KP012  | 100 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | Mild             | None                | 60<br>(Moderate)                  | 0                        |
| CV01KP012  | 100 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP012  | 100 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP014  | 100 µg (18-55 years) | 01          | Post-Dose     | Clinic      | Mild | None             | None                | 0                                 | 0                        |
| CV01KP014  | 100 µg (18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP014  | 100 µg (18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP014  | 100 µg (18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP014  | 100 µg (18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP014  | 100 µg (18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP014  | 100 µg (18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP014  | 100 µg (18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP014  | 100 µg (18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP014  | 100 µg (18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP014  | 100 µg (18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP014  | 100 µg (18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP014  | 100 µg (18-55 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP014  | 100 µg (18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP014  | 100 µg (18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP014  | 100 µg (18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP014  | 100 µg (18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP014  | 100 µg (18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP015  | 25 µg (18-55 years)  | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP015  | 25 µg (18-55 years)  | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP015  | 25 µg (18-55 years)  | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP015  | 25 µg (18-55 years)  | 01          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP015  | 25 µg (18-55 years)  | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP015  | 25 µg (18-55 years)  | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP015  | 25 µg (18-55 years)  | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP015  | 25 µg (18-55 years)  | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP015  | 25 µg (18-55 years)  | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP015  | 25 µg (18-55 years)  | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP015  | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP015  | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP015  | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP015  | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP015  | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP015  | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP015  | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP015  | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP018  | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP018  | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP018  | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP018  | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP018  | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP018  | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP018  | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP018  | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP018  | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP023  | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP023  | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP023  | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP023  | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP023  | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP023  | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP023  | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP023  | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP023  | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP023  | 25 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP023  | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP023  | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP023  | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP023  | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP023  | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP023  | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP023  | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP023  | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP024  | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP024  | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP024  | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP024  | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP024  | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP024  | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP024  | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP024  | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP024  | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP024  | 25 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP024  | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP024  | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP024  | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP024  | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP024  | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP024  | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP024  | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP024  | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP026  | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP026  | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP026  | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP026  | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP026  | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP026  | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP026  | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP026  | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP026  | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP026  | 25 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP026  | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP026  | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP026  | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP026  | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP026  | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP026  | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP026  | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP026  | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP027  | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP027  | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP027  | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP027  | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP027  | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP027  | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP027  | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP027  | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP027  | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP027  | 25 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP027  | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP027  | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP027  | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP027  | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP027  | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP027  | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP027  | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP027  | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP028  | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP028  | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP028  | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP028  | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP028  | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP028  | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP028  | 25 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP028  | 25 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP028  | 25 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP030  | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP030  | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP030  | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP030  | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP030  | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP030  | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP030  | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP030  | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP030  | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP030  | 250 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP030  | 250 µg<br>(18-55 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP030  | 250 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP030  | 250 µg<br>(18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP030  | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP030  | 250 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP030  | 250 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP030  | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP030  | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP031  | 25 µg<br>(18-55 years)  | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP031  | 25 µg<br>(18-55 years)  | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP031  | 25 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild     | Mild             | None                | 20                                | 0                        |
| CV01KP031  | 25 µg<br>(18-55 years) | 02          | Day 2         | MA          | Moderate | Mild             | None                | 20                                | 0                        |
| CV01KP031  | 25 µg<br>(18-55 years) | 02          | Day 3         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP031  | 25 µg<br>(18-55 years) | 02          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP031  | 25 µg<br>(18-55 years) | 02          | Day 5         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP031  | 25 µg<br>(18-55 years) | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP031  | 25 µg<br>(18-55 years) | 02          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP031  | 25 µg<br>(18-55 years) | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP032  | 25 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01KP032  | 25 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP032  | 25 µg<br>(18-55 years) | 01          | Day 2         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP032  | 25 µg<br>(18-55 years) | 01          | Day 3         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP032  | 25 µg<br>(18-55 years) | 01          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP032  | 25 µg<br>(18-55 years) | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP032  | 25 µg<br>(18-55 years)  | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP032  | 25 µg<br>(18-55 years)  | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP032  | 25 µg<br>(18-55 years)  | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP032  | 25 µg<br>(18-55 years)  | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP032  | 25 µg<br>(18-55 years)  | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP032  | 25 µg<br>(18-55 years)  | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP032  | 25 µg<br>(18-55 years)  | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP032  | 25 µg<br>(18-55 years)  | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP032  | 25 µg<br>(18-55 years)  | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP032  | 25 µg<br>(18-55 years)  | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP032  | 25 µg<br>(18-55 years)  | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP032  | 25 µg<br>(18-55 years)  | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP033  | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP033  | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP033  | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | Mild                | 0                                 | 7                        |
| CV01KP033  | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP033  | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP033  | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP033  | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP033  | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP033  | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP033  | 250 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP033  | 250 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild | None             | Mild                | 0                                 | 30 (Mild)                |
| CV01KP033  | 250 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | None             | Mild                | 0                                 | 20                       |
| CV01KP033  | 250 µg<br>(18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP033  | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP033  | 250 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP033  | 250 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP033  | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP033  | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP036  | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP036  | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP036  | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP036  | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP036  | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP036  | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP036  | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP036  | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP036  | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP036  | 250 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP036  | 250 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP036  | 250 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP036  | 250 µg<br>(18-55 years) | 02          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP036  | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP036  | 250 µg<br>(18-55 years) | 02          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP036  | 250 µg<br>(18-55 years) | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP036  | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP036  | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP037  | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP037  | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP037  | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01KP037  | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP037  | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP037  | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP037  | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP037  | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP037  | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP040  | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP040  | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP040  | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | Moderate | None             | Mild                | 0                                 | 30 (Mild)                |
| CV01KP040  | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP040  | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP040  | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP040  | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP040  | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP040  | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP040  | 250 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01KP040  | 250 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP040  | 250 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP040  | 250 µg<br>(18-55 years) | 02          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP040  | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP040  | 250 µg<br>(18-55 years) | 02          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP040  | 250 µg<br>(18-55 years) | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP040  | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP040  | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP041  | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01KP041  | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01KP041  | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01KP041  | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP041  | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP041  | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP041  | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP041  | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP041  | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP041  | 250 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01KP041  | 250 µg<br>(18-55 years) | 02          | Day 1         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01KP041  | 250 µg<br>(18-55 years) | 02          | Day 2         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01KP041  | 250 µg<br>(18-55 years) | 02          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP041  | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP041  | 250 µg<br>(18-55 years) | 02          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP041  | 250 µg<br>(18-55 years) | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP041  | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP041  | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP048  | 250 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01KP048  | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP048  | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP048  | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP048  | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP048  | 250 µg (18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP048  | 250 µg (18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP048  | 250 µg (18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP048  | 250 µg (18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP048  | 250 µg (18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP048  | 250 µg (18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP048  | 250 µg (18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP048  | 250 µg (18-55 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP048  | 250 µg (18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP048  | 250 µg (18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP048  | 250 µg (18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP048  | 250 µg (18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP048  | 250 µg (18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP049  | 250 µg (18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP049  | 250 µg<br>(18-55 years) | 01          | Day 1         | MA          | Moderate | None             | Mild                | 0                                 | 1                        |
| CV01KP049  | 250 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild     | None             | Mild                | 0                                 | 1                        |
| CV01KP049  | 250 µg<br>(18-55 years) | 01          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP049  | 250 µg<br>(18-55 years) | 01          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP049  | 250 µg<br>(18-55 years) | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP049  | 250 µg<br>(18-55 years) | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP049  | 250 µg<br>(18-55 years) | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP049  | 250 µg<br>(18-55 years) | 01          | Day 8         | MA          | None     | Mild             | Mild                | 50<br>(Moderate)                  | 50<br>(Moderate)         |
| CV01KP049  | 250 µg<br>(18-55 years) | 01          | Day 12        | MA          | .        | Mild             | Mild                | 105<br>(Severe)                   | 105<br>(Severe)          |
| CV01KP049  | 250 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01KP049  | 250 µg<br>(18-55 years) | 02          | Day 1         | MA          | Moderate | Mild             | Mild                | 10                                | 60<br>(Moderate)         |
| CV01KP049  | 250 µg<br>(18-55 years) | 02          | Day 2         | MA          | Moderate | Mild             | Mild                | 75<br>(Moderate)                  | 60<br>(Moderate)         |
| CV01KP049  | 250 µg<br>(18-55 years) | 02          | Day 3         | MA          | Mild     | Mild             | Mild                | 105<br>(Severe)                   | 25 (Mild)                |
| CV01KP049  | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | Mild     | Mild             | None                | 60<br>(Moderate)                  | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group    | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|----------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP049  | 250 µg (18-55 years) | 02          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP049  | 250 µg (18-55 years) | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP049  | 250 µg (18-55 years) | 02          | Day 7         | MA          | Not Done | Not Done         | Not Done            | .                                 | .                        |
| CV01KP049  | 250 µg (18-55 years) | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP053  | 250 µg (18-55 years) | 01          | Post-Dose     | Clinic      | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP053  | 250 µg (18-55 years) | 01          | Day 1         | MA          | Moderate | Mild             | None                | 2                                 | 0                        |
| CV01KP053  | 250 µg (18-55 years) | 01          | Day 2         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01KP053  | 250 µg (18-55 years) | 01          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP053  | 250 µg (18-55 years) | 01          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP053  | 250 µg (18-55 years) | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP053  | 250 µg (18-55 years) | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP053  | 250 µg (18-55 years) | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP053  | 250 µg (18-55 years) | 01          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP053  | 250 µg (18-55 years) | 02          | Post-Dose     | Clinic      | Mild     | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group       | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP053  | 250 µg<br>(18-55 years) | 02          | Day 1         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01KP053  | 250 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP053  | 250 µg<br>(18-55 years) | 02          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP053  | 250 µg<br>(18-55 years) | 02          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP053  | 250 µg<br>(18-55 years) | 02          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP053  | 250 µg<br>(18-55 years) | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP053  | 250 µg<br>(18-55 years) | 02          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP053  | 250 µg<br>(18-55 years) | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP059  | 25 µg<br>(≥71 years)    | 01          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01KP059  | 25 µg<br>(≥71 years)    | 01          | Day 1         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP059  | 25 µg<br>(≥71 years)    | 01          | Day 2         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP059  | 25 µg<br>(≥71 years)    | 01          | Day 3         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP059  | 25 µg<br>(≥71 years)    | 01          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP059  | 25 µg<br>(≥71 years)    | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP059  | 25 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP059  | 25 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP059  | 25 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP059  | 25 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP059  | 25 µg (≥71 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP059  | 25 µg (≥71 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP059  | 25 µg (≥71 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP059  | 25 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP059  | 25 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP059  | 25 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP059  | 25 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP059  | 25 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP060  | 25 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP060  | 25 µg (≥71 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP060  | 25 µg (≥71 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP060  | 25 µg (≥71 years) | 01          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP060  | 25 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP060  | 25 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP060  | 25 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP060  | 25 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP060  | 25 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP060  | 25 µg (≥71 years) | 02          | Post-Dose     | Clinic      | Mild | None             | None                | 0                                 | 0                        |
| CV01KP060  | 25 µg (≥71 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP060  | 25 µg (≥71 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP060  | 25 µg (≥71 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP060  | 25 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP060  | 25 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP060  | 25 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP060  | 25 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP060  | 25 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP061  | 25 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP061  | 25 µg (≥71 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP061  | 25 µg (≥71 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP061  | 25 µg (≥71 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP061  | 25 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP061  | 25 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP061  | 25 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP061  | 25 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP061  | 25 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP061  | 25 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP061  | 25 µg (≥71 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP061  | 25 µg (≥71 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP061  | 25 µg (≥71 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP061  | 25 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP061  | 25 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP061  | 25 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP061  | 25 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP061  | 25 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP062  | 25 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP062  | 25 µg (≥71 years) | 01          | Day 1         | MA          | Mild | Mild             | None                | 20                                | 0                        |
| CV01KP062  | 25 µg (≥71 years) | 01          | Day 2         | MA          | Mild | Mild             | None                | 20                                | 20                       |
| CV01KP062  | 25 µg (≥71 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP062  | 25 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP062  | 25 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP062  | 25 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP062  | 25 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP062  | 25 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP062  | 25 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP062  | 25 µg (≥71 years) | 02          | Day 1         | MA          | Mild | None             | Mild                | 0                                 | 75 (Moderate)            |
| CV01KP062  | 25 µg (≥71 years) | 02          | Day 2         | MA          | None | None             | Mild                | 0                                 | .                        |
| CV01KP062  | 25 µg (≥71 years) | 02          | Day 3         | MA          | None | Mild             | None                | 90 (Moderate)                     | 0                        |
| CV01KP062  | 25 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP062  | 25 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP062  | 25 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP062  | 25 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP062  | 25 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP063  | 25 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP063  | 25 µg (≥71 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP063  | 25 µg (≥71 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP063  | 25 µg (≥71 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP063  | 25 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP063  | 25 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP063  | 25 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP063  | 25 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP063  | 25 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP063  | 25 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP063  | 25 µg (≥71 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP063  | 25 µg (≥71 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP063  | 25 µg (≥71 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP063  | 25 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP063  | 25 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP063  | 25 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP063  | 25 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP063  | 25 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group  | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|--------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP064  | 100 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP064  | 100 µg (≥71 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP064  | 100 µg (≥71 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP064  | 100 µg (≥71 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP064  | 100 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP064  | 100 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP064  | 100 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP064  | 100 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP064  | 100 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP064  | 100 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP064  | 100 µg (≥71 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP064  | 100 µg (≥71 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP064  | 100 µg (≥71 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP064  | 100 µg (≥71 years) | 02          | Day 4         | MA          | Mild | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group  | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|--------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP064  | 100 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP064  | 100 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP064  | 100 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP064  | 100 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP065  | 25 µg (≥71 years)  | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP065  | 25 µg (≥71 years)  | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP065  | 25 µg (≥71 years)  | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP065  | 25 µg (≥71 years)  | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP065  | 25 µg (≥71 years)  | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP065  | 25 µg (≥71 years)  | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP065  | 25 µg (≥71 years)  | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP065  | 25 µg (≥71 years)  | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP065  | 25 µg (≥71 years)  | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP065  | 25 µg (≥71 years)  | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP065  | 25 µg (≥71 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP065  | 25 µg (≥71 years) | 02          | Day 2         | MA          | None | Mild             | None                | 4                                 | 0                        |
| CV01KP065  | 25 µg (≥71 years) | 02          | Day 3         | MA          | None | Mild             | None                | 4                                 | 0                        |
| CV01KP065  | 25 µg (≥71 years) | 02          | Day 4         | MA          | None | Mild             | None                | 4                                 | 0                        |
| CV01KP065  | 25 µg (≥71 years) | 02          | Day 5         | MA          | None | Mild             | None                | 5                                 | 0                        |
| CV01KP065  | 25 µg (≥71 years) | 02          | Day 6         | MA          | None | Mild             | None                | 5                                 | 0                        |
| CV01KP065  | 25 µg (≥71 years) | 02          | Day 7         | MA          | None | Mild             | None                | 4                                 | 0                        |
| CV01KP065  | 25 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP066  | 25 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP066  | 25 µg (≥71 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP066  | 25 µg (≥71 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP066  | 25 µg (≥71 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP066  | 25 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP066  | 25 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group  | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|--------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP066  | 25 µg (≥71 years)  | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP066  | 25 µg (≥71 years)  | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP066  | 25 µg (≥71 years)  | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP066  | 25 µg (≥71 years)  | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP066  | 25 µg (≥71 years)  | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP066  | 25 µg (≥71 years)  | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP066  | 25 µg (≥71 years)  | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP066  | 25 µg (≥71 years)  | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP066  | 25 µg (≥71 years)  | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP066  | 25 µg (≥71 years)  | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP066  | 25 µg (≥71 years)  | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP066  | 25 µg (≥71 years)  | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP067  | 100 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP067  | 100 µg (≥71 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group  | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|--------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP067  | 100 µg (≥71 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP067  | 100 µg (≥71 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP067  | 100 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP067  | 100 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP067  | 100 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP067  | 100 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP067  | 100 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP067  | 100 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP067  | 100 µg (≥71 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP067  | 100 µg (≥71 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP067  | 100 µg (≥71 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP067  | 100 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP067  | 100 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP067  | 100 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group  | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|--------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP067  | 100 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP067  | 100 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP068  | 25 µg (≥71 years)  | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP068  | 25 µg (≥71 years)  | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP068  | 25 µg (≥71 years)  | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP068  | 25 µg (≥71 years)  | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP068  | 25 µg (≥71 years)  | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP068  | 25 µg (≥71 years)  | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP068  | 25 µg (≥71 years)  | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP068  | 25 µg (≥71 years)  | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP068  | 25 µg (≥71 years)  | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP068  | 25 µg (≥71 years)  | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP068  | 25 µg (≥71 years)  | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP068  | 25 µg (≥71 years)  | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP068  | 25 µg (≥71 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP068  | 25 µg (≥71 years) | 02          | Day 4         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP068  | 25 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP068  | 25 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP068  | 25 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP068  | 25 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP069  | 25 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP069  | 25 µg (≥71 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP069  | 25 µg (≥71 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP069  | 25 µg (≥71 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP069  | 25 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP069  | 25 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP069  | 25 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP069  | 25 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group  | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|--------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP069  | 25 µg (≥71 years)  | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP069  | 25 µg (≥71 years)  | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP069  | 25 µg (≥71 years)  | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP069  | 25 µg (≥71 years)  | 02          | Day 2         | MA          | Mild | Mild             | Mild                | 80 (Moderate)                     | 80 (Moderate)            |
| CV01KP069  | 25 µg (≥71 years)  | 02          | Day 3         | MA          | None | Mild             | Mild                | 40 (Mild)                         | 40 (Mild)                |
| CV01KP069  | 25 µg (≥71 years)  | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP069  | 25 µg (≥71 years)  | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP069  | 25 µg (≥71 years)  | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP069  | 25 µg (≥71 years)  | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP069  | 25 µg (≥71 years)  | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP071  | 100 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP071  | 100 µg (≥71 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP071  | 100 µg (≥71 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP071  | 100 µg (≥71 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group  | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|--------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP071  | 100 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP071  | 100 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP071  | 100 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP071  | 100 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP071  | 100 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP071  | 100 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP071  | 100 µg (≥71 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP071  | 100 µg (≥71 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP071  | 100 µg (≥71 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP071  | 100 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP071  | 100 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP071  | 100 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP071  | 100 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP071  | 100 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP072  | 25 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP072  | 25 µg (≥71 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP072  | 25 µg (≥71 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP072  | 25 µg (≥71 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP072  | 25 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP072  | 25 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP072  | 25 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP072  | 25 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP072  | 25 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP072  | 25 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP072  | 25 µg (≥71 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP072  | 25 µg (≥71 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP072  | 25 µg (≥71 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP072  | 25 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group  | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|--------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP072  | 25 µg (≥71 years)  | 02          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP072  | 25 µg (≥71 years)  | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP072  | 25 µg (≥71 years)  | 02          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP072  | 25 µg (≥71 years)  | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP073  | 100 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01KP073  | 100 µg (≥71 years) | 01          | Day 1         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP073  | 100 µg (≥71 years) | 01          | Day 2         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP073  | 100 µg (≥71 years) | 01          | Day 3         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP073  | 100 µg (≥71 years) | 01          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP073  | 100 µg (≥71 years) | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP073  | 100 µg (≥71 years) | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP073  | 100 µg (≥71 years) | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP073  | 100 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01KP073  | 100 µg (≥71 years) | 02          | Day 1         | MA          | Moderate | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group  | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|--------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP073  | 100 µg (≥71 years) | 02          | Day 2         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01KP073  | 100 µg (≥71 years) | 02          | Day 3         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP073  | 100 µg (≥71 years) | 02          | Day 4         | MA          | None     | Mild             | None                | .                                 | 0                        |
| CV01KP073  | 100 µg (≥71 years) | 02          | Day 5         | MA          | None     | Mild             | None                | .                                 | 0                        |
| CV01KP073  | 100 µg (≥71 years) | 02          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP073  | 100 µg (≥71 years) | 02          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP073  | 100 µg (≥71 years) | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP075  | 100 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01KP075  | 100 µg (≥71 years) | 01          | Day 1         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP075  | 100 µg (≥71 years) | 01          | Day 2         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01KP075  | 100 µg (≥71 years) | 01          | Day 3         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP075  | 100 µg (≥71 years) | 01          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP075  | 100 µg (≥71 years) | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01KP075  | 100 µg (≥71 years) | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group  | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|--------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP075  | 100 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP075  | 100 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP075  | 100 µg (≥71 years) | 02          | Post-Dose     | Clinic      | Mild | None             | None                | 0                                 | 0                        |
| CV01KP075  | 100 µg (≥71 years) | 02          | Day 1         | MA          | Mild | None             | Mild                | 0                                 | 70 (Moderate)            |
| CV01KP075  | 100 µg (≥71 years) | 02          | Day 2         | MA          | Mild | None             | Mild                | 0                                 | 70 (Moderate)            |
| CV01KP075  | 100 µg (≥71 years) | 02          | Day 3         | MA          | Mild | None             | Mild                | 0                                 | 60 (Moderate)            |
| CV01KP075  | 100 µg (≥71 years) | 02          | Day 4         | MA          | Mild | None             | Mild                | 0                                 | 40 (Mild)                |
| CV01KP075  | 100 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP075  | 100 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP075  | 100 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP075  | 100 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP076  | 100 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP076  | 100 µg (≥71 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP076  | 100 µg (≥71 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group  | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|--------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP076  | 100 µg (≥71 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP076  | 100 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP076  | 100 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP076  | 100 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP076  | 100 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP076  | 100 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP076  | 100 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP076  | 100 µg (≥71 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP076  | 100 µg (≥71 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP076  | 100 µg (≥71 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP076  | 100 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP076  | 100 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP076  | 100 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP076  | 100 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group  | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|--------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP076  | 100 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP077  | 100 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP077  | 100 µg (≥71 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP077  | 100 µg (≥71 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP077  | 100 µg (≥71 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP077  | 100 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP077  | 100 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP077  | 100 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP077  | 100 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP077  | 100 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP077  | 100 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | Mild             | None                | 20                                | 0                        |
| CV01KP077  | 100 µg (≥71 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP077  | 100 µg (≥71 years) | 02          | Day 2         | MA          | Mild | Mild             | Mild                | 80 (Moderate)                     | 60 (Moderate)            |
| CV01KP077  | 100 µg (≥71 years) | 02          | Day 3         | MA          | None | Mild             | None                | 60 (Moderate)                     | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group  | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|--------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP077  | 100 µg (≥71 years) | 02          | Day 4         | MA          | None | Mild             | None                | 40 (Mild)                         | 0                        |
| CV01KP077  | 100 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP077  | 100 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP077  | 100 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP077  | 100 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP078  | 100 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP078  | 100 µg (≥71 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP078  | 100 µg (≥71 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP078  | 100 µg (≥71 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP078  | 100 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP078  | 100 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP078  | 100 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP078  | 100 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP078  | 100 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group  | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|--------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP078  | 100 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP078  | 100 µg (≥71 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP078  | 100 µg (≥71 years) | 02          | Day 2         | MA          | Mild | None             | Mild                | 0                                 | 50 (Moderate)            |
| CV01KP078  | 100 µg (≥71 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP078  | 100 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP078  | 100 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP078  | 100 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP078  | 100 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP078  | 100 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP081  | 100 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP081  | 100 µg (≥71 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP081  | 100 µg (≥71 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP081  | 100 µg (≥71 years) | 01          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP081  | 100 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group  | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|--------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP081  | 100 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP081  | 100 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP081  | 100 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP081  | 100 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP081  | 100 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP081  | 100 µg (≥71 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP081  | 100 µg (≥71 years) | 02          | Day 2         | MA          | Mild | Mild             | None                | 2                                 | 0                        |
| CV01KP081  | 100 µg (≥71 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP081  | 100 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP081  | 100 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP081  | 100 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP081  | 100 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP081  | 100 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP085  | 100 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group  | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|--------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP085  | 100 µg (≥71 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP085  | 100 µg (≥71 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP085  | 100 µg (≥71 years) | 01          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP085  | 100 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP085  | 100 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP085  | 100 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP085  | 100 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP085  | 100 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP085  | 100 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP085  | 100 µg (≥71 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP085  | 100 µg (≥71 years) | 02          | Day 2         | MA          | Mild | Mild             | None                | 30 (Mild)                         | 0                        |
| CV01KP085  | 100 µg (≥71 years) | 02          | Day 3         | MA          | Mild | Mild             | None                | 30 (Mild)                         | 0                        |
| CV01KP085  | 100 µg (≥71 years) | 02          | Day 4         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP085  | 100 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group   | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|---------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP085  | 100 µg (≥71 years)  | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP085  | 100 µg (≥71 years)  | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP085  | 100 µg (≥71 years)  | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP092  | 50 µg (18-55 years) | 01          | Post-Dose     | Clinic      | Mild | None             | None                | 0                                 | 0                        |
| CV01KP092  | 50 µg (18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP092  | 50 µg (18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP092  | 50 µg (18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP092  | 50 µg (18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP092  | 50 µg (18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP092  | 50 µg (18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP092  | 50 µg (18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP092  | 50 µg (18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP092  | 50 µg (18-55 years) | 02          | Post-Dose     | Clinic      | Mild | None             | None                | 0                                 | 0                        |
| CV01KP092  | 50 µg (18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP092  | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | None | Mild             | None                | 3                                 | 0                        |
| CV01KP092  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP092  | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP092  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP092  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP092  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP092  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP094  | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP094  | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP094  | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP094  | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP094  | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP094  | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP094  | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP094  | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP094  | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP094  | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP094  | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP094  | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP094  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP094  | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP094  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP094  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP094  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP094  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP095  | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP095  | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP095  | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP095  | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP095  | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP095  | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP095  | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP095  | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP095  | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP095  | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP095  | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP095  | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP095  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP095  | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP095  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP095  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP095  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP095  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP096  | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP096  | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP096  | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP096  | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP096  | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP096  | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP096  | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP096  | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP096  | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP096  | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP096  | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP096  | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP096  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP096  | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP096  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP096  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP096  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP096  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP097  | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP097  | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP097  | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP097  | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP097  | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP097  | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP097  | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP097  | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP097  | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP097  | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP097  | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP097  | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP097  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP097  | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP097  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP097  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP097  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP097  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP098  | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | Mild | None             | None                | 0                                 | 0                        |
| CV01KP098  | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | None             | Mild                | 0                                 | 10                       |
| CV01KP098  | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP098  | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP098  | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP098  | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP098  | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP098  | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP098  | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP098  | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP098  | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP098  | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP098  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP098  | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP098  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP098  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP098  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP098  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP101  | 50 µg<br>(18-55 years) | 01          | Post-Dose     | Clinic      | Mild | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP101  | 50 µg<br>(18-55 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP101  | 50 µg<br>(18-55 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP101  | 50 µg<br>(18-55 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP101  | 50 µg<br>(18-55 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP101  | 50 µg<br>(18-55 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP101  | 50 µg<br>(18-55 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP101  | 50 µg<br>(18-55 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP101  | 50 µg<br>(18-55 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP101  | 50 µg<br>(18-55 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01KP101  | 50 µg<br>(18-55 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP101  | 50 µg<br>(18-55 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01KP101  | 50 µg<br>(18-55 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP101  | 50 µg<br>(18-55 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP101  | 50 µg<br>(18-55 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01KP101  | 50 µg<br>(18-55 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP101  | 50 µg<br>(18-55 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01KP101  | 50 µg<br>(18-55 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR002  | 50 µg<br>(≥71 years)   | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR002  | 50 µg<br>(≥71 years)   | 01          | Day 1         | MA          | None | None             | None                | 6                                 | 0                        |
| CV01VR002  | 50 µg<br>(≥71 years)   | 01          | Day 2         | MA          | None | None             | None                | 6                                 | 0                        |
| CV01VR002  | 50 µg<br>(≥71 years)   | 01          | Day 3         | MA          | None | None             | None                | 6                                 | 0                        |
| CV01VR002  | 50 µg<br>(≥71 years)   | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR002  | 50 µg<br>(≥71 years)   | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR002  | 50 µg<br>(≥71 years)   | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR002  | 50 µg<br>(≥71 years)   | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR002  | 50 µg<br>(≥71 years)   | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR002  | 50 µg<br>(≥71 years)   | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR002  | 50 µg<br>(≥71 years)   | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group   | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|---------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR002  | 50 µg (≥71 years)   | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR002  | 50 µg (≥71 years)   | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR002  | 50 µg (≥71 years)   | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR002  | 50 µg (≥71 years)   | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR002  | 50 µg (≥71 years)   | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR002  | 50 µg (≥71 years)   | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR002  | 50 µg (≥71 years)   | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR003  | 50 µg (56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR003  | 50 µg (56-70 years) | 01          | Day 1         | MA          | Mild | None             | Moderate            | 0                                 | 55 (Moderate)            |
| CV01VR003  | 50 µg (56-70 years) | 01          | Day 2         | MA          | Mild | None             | Mild                | 0                                 | 50 (Moderate)            |
| CV01VR003  | 50 µg (56-70 years) | 01          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR003  | 50 µg (56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR003  | 50 µg (56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR003  | 50 µg (56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR003  | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR003  | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR003  | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR003  | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR003  | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR003  | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR003  | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR003  | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR003  | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR003  | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR003  | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR004  | 50 µg<br>(≥71 years)   | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR004  | 50 µg<br>(≥71 years)   | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR004  | 50 µg<br>(≥71 years)   | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR004  | 50 µg (≥71 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR004  | 50 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR004  | 50 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR004  | 50 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR004  | 50 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR004  | 50 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR004  | 50 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR004  | 50 µg (≥71 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR004  | 50 µg (≥71 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR004  | 50 µg (≥71 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR004  | 50 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR004  | 50 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR004  | 50 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR004  | 50 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR004  | 50 µg<br>(≥71 years)   | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR005  | 50 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR005  | 50 µg<br>(56-70 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR005  | 50 µg<br>(56-70 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR005  | 50 µg<br>(56-70 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR005  | 50 µg<br>(56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR005  | 50 µg<br>(56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR005  | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR005  | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR005  | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR005  | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR006  | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR006  | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR008  | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR008  | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Day 3         | MA          | Mild | None             | Moderate            | 0                                 | 80<br>(Moderate)         |
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR009  | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR009  | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR011  | 50 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR011  | 50 µg<br>(56-70 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR011  | 50 µg<br>(56-70 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR011  | 50 µg<br>(56-70 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR011  | 50 µg<br>(56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR011  | 50 µg<br>(56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR011  | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR011  | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR011  | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR011  | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR011  | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR011  | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR011  | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR011  | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR011  | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR011  | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR011  | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR011  | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR013  | 50 µg<br>(≥71 years)   | 01          | Post-Dose     | Clinic      | Mild | None             | None                | 0                                 | 0                        |
| CV01VR013  | 50 µg<br>(≥71 years)   | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR013  | 50 µg<br>(≥71 years)   | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR013  | 50 µg<br>(≥71 years)   | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR013  | 50 µg<br>(≥71 years)   | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR013  | 50 µg<br>(≥71 years)   | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR013  | 50 µg<br>(≥71 years)   | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR013  | 50 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR013  | 50 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR013  | 50 µg (≥71 years) | 02          | Post-Dose     | Clinic      | Mild | None             | None                | 0                                 | 0                        |
| CV01VR013  | 50 µg (≥71 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR013  | 50 µg (≥71 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR013  | 50 µg (≥71 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR013  | 50 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR013  | 50 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR013  | 50 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR013  | 50 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR013  | 50 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR014  | 50 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR014  | 50 µg (≥71 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR014  | 50 µg (≥71 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR014  | 50 µg (≥71 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR014  | 50 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR014  | 50 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR014  | 50 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR014  | 50 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR014  | 50 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR014  | 50 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR014  | 50 µg (≥71 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR014  | 50 µg (≥71 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR014  | 50 µg (≥71 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR014  | 50 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR014  | 50 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR014  | 50 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR014  | 50 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain     | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|----------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR014  | 50 µg<br>(≥71 years)   | 02          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01VR016  | 50 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01VR016  | 50 µg<br>(56-70 years) | 01          | Day 1         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01VR016  | 50 µg<br>(56-70 years) | 01          | Day 2         | MA          | Mild     | None             | None                | 0                                 | 0                        |
| CV01VR016  | 50 µg<br>(56-70 years) | 01          | Day 3         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01VR016  | 50 µg<br>(56-70 years) | 01          | Day 4         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01VR016  | 50 µg<br>(56-70 years) | 01          | Day 5         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01VR016  | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01VR016  | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01VR016  | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | None     | None             | None                | 0                                 | 0                        |
| CV01VR016  | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None     | None             | None                | 0                                 | 0                        |
| CV01VR016  | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | Moderate | None             | None                | 0                                 | 0                        |
| CV01VR016  | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | Moderate | Moderate         | Moderate            | 95<br>(Moderate)                  | 60<br>(Moderate)         |
| CV01VR016  | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | Mild     | Severe           | Moderate            | 120<br>(Severe)                   | 80<br>(Moderate)         |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR016  | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | Mild | Moderate         | Moderate            | 85<br>(Moderate)                  | 65<br>(Moderate)         |
| CV01VR016  | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | Moderate            | 0                                 | 70<br>(Moderate)         |
| CV01VR016  | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | Mild                | 0                                 | 40 (Mild)                |
| CV01VR016  | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR016  | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR017  | 50 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR017  | 50 µg<br>(56-70 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR017  | 50 µg<br>(56-70 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR017  | 50 µg<br>(56-70 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR017  | 50 µg<br>(56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR017  | 50 µg<br>(56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR017  | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR017  | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR017  | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR017  | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR017  | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR017  | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR017  | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR017  | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR017  | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR017  | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR017  | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR017  | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR018  | 50 µg<br>(≥71 years)   | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR018  | 50 µg<br>(≥71 years)   | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR018  | 50 µg<br>(≥71 years)   | 01          | Day 2         | MA          | None | None             | None                | 3                                 | 10                       |
| CV01VR018  | 50 µg<br>(≥71 years)   | 01          | Day 3         | MA          | None | None             | None                | 5                                 | 20                       |
| CV01VR018  | 50 µg<br>(≥71 years)   | 01          | Day 4         | MA          | None | None             | Mild                | 9                                 | 25 (Mild)                |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR018  | 50 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | Mild                | 7                                 | 35 (Mild)                |
| CV01VR018  | 50 µg (≥71 years) | 01          | Day 6         | MA          | Mild | None             | Mild                | 15                                | 25 (Mild)                |
| CV01VR018  | 50 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 10                                | 20                       |
| CV01VR018  | 50 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | Mild                | 20                                | 32 (Mild)                |
| CV01VR018  | 50 µg (≥71 years) | 01          | Day 10        | MA          | .    | .                | Mild                | 20                                | 32 (Mild)                |
| CV01VR018  | 50 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR018  | 50 µg (≥71 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR018  | 50 µg (≥71 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR018  | 50 µg (≥71 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR018  | 50 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 10                       |
| CV01VR018  | 50 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 20                       |
| CV01VR018  | 50 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR018  | 50 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR018  | 50 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR021  | 50 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | Mild                | 0                                 | 17                       |
| CV01VR021  | 50 µg (≥71 years) | 01          | Day 1         | MA          | Mild | Mild             | Mild                | 4                                 | 3                        |
| CV01VR021  | 50 µg (≥71 years) | 01          | Day 2         | MA          | Mild | Mild             | Mild                | 4                                 | 3                        |
| CV01VR021  | 50 µg (≥71 years) | 01          | Day 3         | MA          | Mild | Mild             | Mild                | 3                                 | 2                        |
| CV01VR021  | 50 µg (≥71 years) | 01          | Day 4         | MA          | Mild | Mild             | Mild                | 2                                 | 1                        |
| CV01VR021  | 50 µg (≥71 years) | 01          | Day 5         | MA          | Mild | None             | Mild                | 0                                 | 1                        |
| CV01VR021  | 50 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR021  | 50 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR021  | 50 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR021  | 50 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR021  | 50 µg (≥71 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR021  | 50 µg (≥71 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR021  | 50 µg (≥71 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR021  | 50 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR021  | 50 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR021  | 50 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR021  | 50 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR021  | 50 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR023  | 50 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR023  | 50 µg (≥71 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR023  | 50 µg (≥71 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR023  | 50 µg (≥71 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR023  | 50 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR023  | 50 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR023  | 50 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR023  | 50 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR023  | 50 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR023  | 50 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group   | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|---------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR023  | 50 µg (≥71 years)   | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR023  | 50 µg (≥71 years)   | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR023  | 50 µg (≥71 years)   | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR023  | 50 µg (≥71 years)   | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR023  | 50 µg (≥71 years)   | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR023  | 50 µg (≥71 years)   | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR023  | 50 µg (≥71 years)   | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR023  | 50 µg (≥71 years)   | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR024  | 50 µg (56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR024  | 50 µg (56-70 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR024  | 50 µg (56-70 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR024  | 50 µg (56-70 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR024  | 50 µg (56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR024  | 50 µg (56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR024  | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR024  | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR024  | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR024  | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR024  | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR024  | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR024  | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR024  | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR024  | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR024  | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR024  | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR024  | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR028  | 50 µg<br>(56-70 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR028  | 50 µg<br>(56-70 years) | 01          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR028  | 50 µg<br>(56-70 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR028  | 50 µg<br>(56-70 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR028  | 50 µg<br>(56-70 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR028  | 50 µg<br>(56-70 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR028  | 50 µg<br>(56-70 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR028  | 50 µg<br>(56-70 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR028  | 50 µg<br>(56-70 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR028  | 50 µg<br>(56-70 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR028  | 50 µg<br>(56-70 years) | 02          | Day 1         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR028  | 50 µg<br>(56-70 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR028  | 50 µg<br>(56-70 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR028  | 50 µg<br>(56-70 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR028  | 50 µg<br>(56-70 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR028  | 50 µg<br>(56-70 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group      | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|------------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR028  | 50 µg<br>(56-70 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR028  | 50 µg<br>(56-70 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR030  | 50 µg<br>(≥71 years)   | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR030  | 50 µg<br>(≥71 years)   | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR030  | 50 µg<br>(≥71 years)   | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR030  | 50 µg<br>(≥71 years)   | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR030  | 50 µg<br>(≥71 years)   | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR030  | 50 µg<br>(≥71 years)   | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR030  | 50 µg<br>(≥71 years)   | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR030  | 50 µg<br>(≥71 years)   | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR030  | 50 µg<br>(≥71 years)   | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR030  | 50 µg<br>(≥71 years)   | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR030  | 50 µg<br>(≥71 years)   | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR030  | 50 µg<br>(≥71 years)   | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR030  | 50 µg (≥71 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR030  | 50 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR030  | 50 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR030  | 50 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR030  | 50 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR030  | 50 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR035  | 50 µg (≥71 years) | 01          | Post-Dose     | Clinic      | Mild | None             | None                | 0                                 | 0                        |
| CV01VR035  | 50 µg (≥71 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR035  | 50 µg (≥71 years) | 01          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR035  | 50 µg (≥71 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR035  | 50 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR035  | 50 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR035  | 50 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR035  | 50 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR035  | 50 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR035  | 50 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR035  | 50 µg (≥71 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR035  | 50 µg (≥71 years) | 02          | Day 2         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR035  | 50 µg (≥71 years) | 02          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR035  | 50 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR035  | 50 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR035  | 50 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR035  | 50 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR035  | 50 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR037  | 50 µg (≥71 years) | 01          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR037  | 50 µg (≥71 years) | 01          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR037  | 50 µg (≥71 years) | 01          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR037  | 50 µg (≥71 years) | 01          | Day 3         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|------------|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| CV01VR037  | 50 µg (≥71 years) | 01          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR037  | 50 µg (≥71 years) | 01          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR037  | 50 µg (≥71 years) | 01          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR037  | 50 µg (≥71 years) | 01          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR037  | 50 µg (≥71 years) | 01          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR037  | 50 µg (≥71 years) | 02          | Post-Dose     | Clinic      | None | None             | None                | 0                                 | 0                        |
| CV01VR037  | 50 µg (≥71 years) | 02          | Day 1         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR037  | 50 µg (≥71 years) | 02          | Day 2         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR037  | 50 µg (≥71 years) | 02          | Day 3         | MA          | Mild | None             | None                | 0                                 | 0                        |
| CV01VR037  | 50 µg (≥71 years) | 02          | Day 4         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR037  | 50 µg (≥71 years) | 02          | Day 5         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR037  | 50 µg (≥71 years) | 02          | Day 6         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR037  | 50 µg (≥71 years) | 02          | Day 7         | MA          | None | None             | None                | 0                                 | 0                        |
| CV01VR037  | 50 µg (≥71 years) | 02          | Day 8         | MA          | None | None             | None                | 0                                 | 0                        |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix C2 (continued)**  
**Solicited Local Events**

| Subject ID  | Vaccination Group | Dose Number | Post Dose Day | Assessment* | Pain | Erythema/redness | Induration/swelling | Erythema/redness measurement (mm) | Induration/swelling (mm) |
|---|-------------------|-------------|---------------|-------------|------|------------------|---------------------|-----------------------------------|--------------------------|
| <p>*MA = Data reported by subject on the Memory Aid and reviewed by clinic staff and reported in Solicited Events eCRF.<br/>Clinic = Data collected by clinic staff during physical exam or symptom assessment (treatment administration record, in-clinic assessment, etc.)<br/>See <a href="#">Appendix D</a> for listing of attributions for systemic events contributing toward halting criteria.</p> |                   |             |               |             |      |                  |                     |                                   |                          |

**APPENDIX D:**  
**Attribution for Systemic Solicited Events that Contribute to Halting Criteria**

| Subject ID | Vaccination Group       | Systemic Reaction | Dose Number | Post-Dose Day | Severity | Attributed to Alternate Etiology? |
|------------|-------------------------|-------------------|-------------|---------------|----------|-----------------------------------|
| CV01EM027  | 25 µg<br>(56-70 years)  | Fever             | 02          | 2             | SEVERE   | No                                |
| CV01EM051  | 50 µg<br>(18-55 years)  | Headache          | 02          | 2             | SEVERE   | No                                |
| CV01KP040  | 250 µg<br>(18-55 years) | Fatigue           | 02          | 2             | SEVERE   | No                                |
| CV01KP040  | 250 µg<br>(18-55 years) | Feverishness      | 02          | 1             | SEVERE   | No                                |
| CV01KP040  | 250 µg<br>(18-55 years) | Feverishness      | 02          | 2             | SEVERE   | No                                |
| CV01KP040  | 250 µg<br>(18-55 years) | Headache          | 02          | 2             | SEVERE   | No                                |
| CV01KP040  | 250 µg<br>(18-55 years) | Fever             | 02          | 2             | SEVERE   | No                                |
| CV01KP041  | 250 µg<br>(18-55 years) | Fatigue           | 02          | 2             | SEVERE   | No                                |
| CV01KP041  | 250 µg<br>(18-55 years) | Feverishness      | 02          | 2             | SEVERE   | No                                |
| CV01KP048  | 250 µg<br>(18-55 years) | Feverishness      | 02          | 2             | SEVERE   | No                                |
| CV01KP048  | 250 µg<br>(18-55 years) | Myalgia           | 02          | 2             | SEVERE   | No                                |
| CV01KP048  | 250 µg<br>(18-55 years) | Nausea            | 02          | 2             | SEVERE   | No                                |
| CV01KP077  | 100 µg<br>(≥71 years)   | Fatigue           | 02          | 2             | SEVERE   | No                                |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**APPENDIX E:**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | -1                | -22              | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 1                 | 1                | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 8                 | 8                | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 29                | 29               | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 36                | 36               | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | -1                | -22              | Alkaline Phosphatase (U/L)     | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 45                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 8                 | 8                | Alkaline Phosphatase (U/L)     | 48                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 29                | 29               | Alkaline Phosphatase (U/L)     | 50                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 36                | 36               | Alkaline Phosphatase (U/L)     | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | -1                | -22              | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 29                | 29               | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 36                | 36               | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | -1                | -22              | Creatinine (mg/dL)               | 0.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 1                 | 1                | Creatinine (mg/dL)               | 0.88              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 8                 | 8                | Creatinine (mg/dL)               | 0.88              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 29                | 29               | Creatinine (mg/dL)               | 0.82              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 36                | 36               | Creatinine (mg/dL)               | 0.95              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | -1                | -22              | Hemoglobin (g/dL)                | 15.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 1                 | 1                | Hemoglobin (g/dL)               | 14.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 8                 | 8                | Hemoglobin (g/dL)               | 14.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 29                | 29               | Hemoglobin (g/dL)               | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 36                | 36               | Hemoglobin (g/dL)               | 14.0 (Mild)       | NOT RELATED                 | Grade 1, due to phlebotomy procedure | NA- NOT APPLICABLE                  | No                                  |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | -1                | -22              | PT (seconds)                    | 11.8 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | -1                | -14              | PT (seconds)                    | 10.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | -1                | -22              | PTT (seconds)                   | 34.0 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | -1                | -22              | Platelets (10 <sup>3</sup> /uL) | 190               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 182               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 204               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 197               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 212               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | -1                | -22              | Serum Lipase (U/L)              | 12.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 1                 | 1                | Serum Lipase (U/L)           | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 8                 | 8                | Serum Lipase (U/L)           | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 29                | 29               | Serum Lipase (U/L)           | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 36                | 36               | Serum Lipase (U/L)           | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | -1                | -22              | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 8                 | 8                | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 29                | 29               | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 36                | 36               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | -1                | -22              | WBC (10 <sup>3</sup> /uL)    | 3.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | -1                | -15              | WBC (10 <sup>3</sup> /uL)    | 4.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 4.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)    | 4.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 4.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM003  | 250 µg (18-55 years) | MALE | 30          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 4.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | Alanine Aminotransferase (U/L) | 26                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Alanine Aminotransferase (U/L) | 26                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 8                 | 7                | Alanine Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 29                | 28               | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 36                | 35               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | Alkaline Phosphatase (U/L)     | 82                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 85                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 8                 | 7                | Alkaline Phosphatase (U/L)     | 86                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 29                | 28               | Alkaline Phosphatase (U/L)     | 75                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 36                | 35               | Alkaline Phosphatase (U/L)       | 81                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 29                | 28               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 36                | 35               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | Creatinine (mg/dL)               | 0.92              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Creatinine (mg/dL)               | 1.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 8                 | 7                | Creatinine (mg/dL)               | 1.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 29                | 28               | Creatinine (mg/dL)               | 0.86              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 36                | 35               | Creatinine (mg/dL)               | 0.93              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology       | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--|-------------------------------------|-------------------------------------|
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | Hemoglobin (g/dL)               | 15.5              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Hemoglobin (g/dL)               | 15.6              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 8                 | 7                | Hemoglobin (g/dL)               | 15.9              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 29                | 28               | Hemoglobin (g/dL)               | 15.1 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedures phlebotomy | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 36                | 35               | Hemoglobin (g/dL)               | 14.7 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy  | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | PT (seconds)                    | 10.5              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | PTT (seconds)                   | 32.0              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | Platelets (10 <sup>3</sup> /uL) | 332               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 334               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 358               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 29                | 28               | Platelets (10 <sup>3</sup> /uL) | 343               | N/A                         | N/A  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 366               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | Serum Lipase (U/L)              | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Serum Lipase (U/L)              | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 8                 | 7                | Serum Lipase (U/L)              | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 29                | 28               | Serum Lipase (U/L)              | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 36                | 35               | Serum Lipase (U/L)              | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 8                 | 7                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 29                | 28               | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 36                | 35               | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | WBC (10 <sup>3</sup> /uL)       | 5.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)       | 6.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM004  | 100 µg (18-55 years) | MALE   | 32          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 6.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE   | 32          | 29                | 28               | WBC (10 <sup>3</sup> /uL)      | 6.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM004  | 100 µg (18-55 years) | MALE   | 32          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 5.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | -1                | -4               | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 1                 | 1                | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 8                 | 8                | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 29                | 28               | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 36                | 35               | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | -1                | -4               | Alkaline Phosphatase (U/L)     | 57                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 54                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 8                 | 8                | Alkaline Phosphatase (U/L)     | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 29                | 28               | Alkaline Phosphatase (U/L)       | 56                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 36                | 35               | Alkaline Phosphatase (U/L)       | 62                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | -1                | -4               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 29                | 28               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 36                | 35               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | -1                | -4               | Creatinine (mg/dL)               | 0.88              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 1                 | 1                | Creatinine (mg/dL)               | 0.82              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 8                 | 8                | Creatinine (mg/dL)               | 0.79              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 29                | 28               | Creatinine (mg/dL)               | 0.78              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology       | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--|-------------------------------------|-------------------------------------|
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 36                | 35               | Creatinine (mg/dL)              | 0.77              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | -1                | -4               | Hemoglobin (g/dL)               | 14.1              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 1                 | 1                | Hemoglobin (g/dL)               | 14.3              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 8                 | 8                | Hemoglobin (g/dL)               | 13.7 (Mild)       | NOT RELATED                 | Due to study procedure - phlebotomy        | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 29                | 28               | Hemoglobin (g/dL)               | 13.8 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedures phlebotomy | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 36                | 35               | Hemoglobin (g/dL)               | 13.8 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy  | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | -1                | -4               | PT (seconds)                    | 10.6              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | -1                | -4               | PTT (seconds)                   | 28.0              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | -1                | -4               | Platelets (10 <sup>3</sup> /uL) | 201               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 200               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 217               | N/A                         | N/A  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 29                | 28               | Platelets (10 <sup>3</sup> /uL) | 206               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 238               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | -1                | -4               | Serum Lipase (U/L)              | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 1                 | 1                | Serum Lipase (U/L)              | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 8                 | 8                | Serum Lipase (U/L)              | 23.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 29                | 28               | Serum Lipase (U/L)              | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 36                | 35               | Serum Lipase (U/L)              | 23.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | -1                | -4               | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 29                | 28               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 36                | 35               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | -1                | -4               | WBC (10 <sup>3</sup> /uL)       | 7.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 29                | 28               | WBC (10 <sup>3</sup> /uL)      | 4.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM005  | 100 µg (18-55 years) | FEMALE | 28          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 5.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE   | 46          | -1                | -4               | Alanine Aminotransferase (U/L) | 30                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE   | 46          | 1                 | 1                | Alanine Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE   | 46          | 8                 | 7                | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE   | 46          | 29                | 28               | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE   | 46          | 36                | 34               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE   | 46          | -1                | -4               | Alkaline Phosphatase (U/L)     | 57                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE   | 46          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 29                | 28               | Alkaline Phosphatase (U/L)       | 51                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 36                | 34               | Alkaline Phosphatase (U/L)       | 51                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | -1                | -4               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 29                | 28               | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 36                | 34               | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | -1                | -4               | Creatinine (mg/dL)               | 0.95              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 1                 | 1                | Creatinine (mg/dL)               | 0.97              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 8                 | 7                | Creatinine (mg/dL)               | 0.96              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 29                | 28               | Creatinine (mg/dL)              | 0.97              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 36                | 34               | Creatinine (mg/dL)              | 0.97              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | -1                | -4               | Hemoglobin (g/dL)               | 15.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 1                 | 1                | Hemoglobin (g/dL)               | 15.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 8                 | 7                | Hemoglobin (g/dL)               | 15.6 (Mild)       | NOT RELATED                 | Due to phlebotomy (study procedure)  | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 29                | 28               | Hemoglobin (g/dL)               | 15.2 (Mild)       | NOT RELATED                 | Due to study procedure phlebotomy    | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 36                | 34               | Hemoglobin (g/dL)               | 14.4 (Mild)       | NOT RELATED                 | Due to study procedure phlebotomy    | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | -1                | -4               | PT (seconds)                    | 10.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | -1                | -4               | PTT (seconds)                   | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | -1                | -4               | Platelets (10 <sup>3</sup> /uL) | 163               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 185               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 195               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 29                | 28               | Platelets (10 <sup>3</sup> /uL) | 170               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 36                | 34               | Platelets (10 <sup>3</sup> /uL) | 162               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | -1                | -4               | Serum Lipase (U/L)              | 12.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 1                 | 1                | Serum Lipase (U/L)              | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 8                 | 7                | Serum Lipase (U/L)              | 12.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 29                | 28               | Serum Lipase (U/L)              | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 36                | 34               | Serum Lipase (U/L)              | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | -1                | -4               | Total Bilirubin (mg/dL)         | 1.5 (Mild)        | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | -1                | -2               | Total Bilirubin (mg/dL)         | 1.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 1                 | 1                | Total Bilirubin (mg/dL)         | 1.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 8                 | 7                | Total Bilirubin (mg/dL)         | 1.1               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology  | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|---------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 29                | 28               | Total Bilirubin (mg/dL)        | 1.4 (Mild)        | NOT RELATED                 | Grade 1 Similar to baseline bilirubin | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 36                | 34               | Total Bilirubin (mg/dL)        | 1.3               | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 57                | 55               | Total Bilirubin (mg/dL)        | 1.1               | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | -1                | -4               | WBC (10 <sup>3</sup> /uL)      | 4.80              | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.10              | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 4.80              | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 29                | 28               | WBC (10 <sup>3</sup> /uL)      | 5.30              | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01EM007  | 100 µg (18-55 years) | MALE | 46          | 36                | 34               | WBC (10 <sup>3</sup> /uL)      | 3.90              | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | Alanine Aminotransferase (U/L) | 26                | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Alanine Aminotransferase (U/L) | 34                | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 8                 | 8                | Alanine Aminotransferase (U/L) | 34                | N/A                         | N/A                                   | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 29                | 29               | Alanine Aminotransferase (U/L)   | 41                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 36                | 36               | Alanine Aminotransferase (U/L)   | 30                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | Alkaline Phosphatase (U/L)       | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 56                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 58                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 29                | 29               | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 36                | 36               | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 29                | 29               | Aspartate Aminotransferase (U/L) | 26                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 36                | 36               | Aspartate Aminotransferase (U/L) | 26                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | Creatinine (mg/dL)               | 0.95              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Creatinine (mg/dL)               | 1.04              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 8                 | 8                | Creatinine (mg/dL)               | 0.93              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 29                | 29               | Creatinine (mg/dL)               | 1.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 36                | 36               | Creatinine (mg/dL)               | 0.96              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | Hemoglobin (g/dL)                | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Hemoglobin (g/dL)                | 14.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 8                 | 8                | Hemoglobin (g/dL)                | 14.6 (Mild)       | NOT RELATED                 | Due to study procedure - phlebotomy  | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 29                | 29               | Hemoglobin (g/dL)                | 15.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 36                | 36               | Hemoglobin (g/dL)                | 14.3 (Mild)       | NOT RELATED                 | study procedure phlebotomy           | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | PT (seconds)                     | 11.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | PTT (seconds)                   | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | Platelets (10 <sup>3</sup> /uL) | 215               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 206               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 221               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 219               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 237               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | Serum Lipase (U/L)              | 20.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Serum Lipase (U/L)              | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 8                 | 8                | Serum Lipase (U/L)              | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 29                | 29               | Serum Lipase (U/L)              | 19.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 36                | 36               | Serum Lipase (U/L)              | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | -1                | -4               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM009  | 100 µg (18-55 years) | MALE   | 32          | 8                 | 8                | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE   | 32          | 29                | 29               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE   | 32          | 36                | 36               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE   | 32          | -1                | -4               | WBC (10 <sup>3</sup> /uL)      | 4.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE   | 32          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE   | 32          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE   | 32          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM009  | 100 µg (18-55 years) | MALE   | 32          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 5.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | -1                | -4               | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 1                 | 1                | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 8                 | 8                | Alanine Aminotransferase (U/L) | 8                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 29                | 29               | Alanine Aminotransferase (U/L)   | 7                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 36                | 35               | Alanine Aminotransferase (U/L)   | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | -1                | -4               | Alkaline Phosphatase (U/L)       | 68                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 65                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 69                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 29                | 29               | Alkaline Phosphatase (U/L)       | 70                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 36                | 35               | Alkaline Phosphatase (U/L)       | 68                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | -1                | -4               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 29                | 29               | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology      | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 36                | 35               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | -1                | -4               | Creatinine (mg/dL)               | 0.80              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 1                 | 1                | Creatinine (mg/dL)               | 0.77              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 8                 | 8                | Creatinine (mg/dL)               | 0.79              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 29                | 29               | Creatinine (mg/dL)               | 0.79              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 36                | 35               | Creatinine (mg/dL)               | 0.73              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | -1                | -4               | Hemoglobin (g/dL)                | 12.3              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 1                 | 1                | Hemoglobin (g/dL)                | 12.2              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 8                 | 8                | Hemoglobin (g/dL)                | 12.5              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 29                | 29               | Hemoglobin (g/dL)                | 12.6              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 36                | 35               | Hemoglobin (g/dL)                | 12.0 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | -1                | -4               | PT (seconds)                     | 11.2              | N/A                         | N/A                                       | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | -1                | -4               | PTT (seconds)                   | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | -1                | -4               | Platelets (10 <sup>3</sup> /uL) | 222               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 226               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 252               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 227               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 231               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | -1                | -4               | Serum Lipase (U/L)              | 53.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 1                 | 1                | Serum Lipase (U/L)              | 54.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 8                 | 8                | Serum Lipase (U/L)              | 53.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 29                | 29               | Serum Lipase (U/L)              | 78.0 (Mild)       | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 36                | 35               | Serum Lipase (U/L)              | 70.0 (Mild)       | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 57                | 56               | Serum Lipase (U/L)              | 77.0 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 119               | 113              | Serum Lipase (U/L)              | 44.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology                                      | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | -1                | -4               | Total Bilirubin (mg/dL)      | 0.3               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 8                 | 8                | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 29                | 29               | Total Bilirubin (mg/dL)      | 0.3               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 36                | 35               | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | -1                | -4               | WBC (10 <sup>3</sup> /uL)    | 4.80              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 3.20 (Mild)       | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)    | 2.80 (Mild)       | NOT RELATED                 | Grade I - similar to Grade I that was present prior to receipt of vaccine | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 29                | 29               | WBC (10 <sup>3</sup> /uL)    | 4.30              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 36                | 35               | WBC (10 <sup>3</sup> /uL)    | 3.00 (Mild)       | NOT RELATED                 | Grade 1 Similar to her baseline   | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM010  | 100 µg (18-55 years) | FEMALE | 23          | 57                | 56               | WBC (10 <sup>3</sup> /uL)    | 4.60              | N/A                         | N/A   | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | -1                | -4               | Alanine Aminotransferase (U/L)   | 32                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 28                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 8                 | 8                | Alanine Aminotransferase (U/L)   | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 29                | 29               | Alanine Aminotransferase (U/L)   | 30                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 36                | 36               | Alanine Aminotransferase (U/L)   | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | -1                | -4               | Alkaline Phosphatase (U/L)       | 77                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 78                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 75                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 29                | 29               | Alkaline Phosphatase (U/L)       | 68                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 36                | 36               | Alkaline Phosphatase (U/L)       | 69                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | -1                | -4               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 29                | 29               | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 36                | 36               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | -1                | -4               | Creatinine (mg/dL)               | 1.08              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 1                 | 1                | Creatinine (mg/dL)               | 1.16              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 8                 | 8                | Creatinine (mg/dL)               | 1.15              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 29                | 29               | Creatinine (mg/dL)               | 1.13              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 36                | 36               | Creatinine (mg/dL)               | 1.02              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | -1                | -4               | Hemoglobin (g/dL)                | 16.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 1                 | 1                | Hemoglobin (g/dL)                | 16.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology       | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--|-------------------------------------|-------------------------------------|
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 8                 | 8                | Hemoglobin (g/dL)               | 15.5 (Mild)       | NOT RELATED                 | Due to study - phlebotomy                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 29                | 29               | Hemoglobin (g/dL)               | 15.3 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedures phlebotomy | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 36                | 36               | Hemoglobin (g/dL)               | 15.9 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy  | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | -1                | -4               | PT (seconds)                    | 10.9              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | -1                | -4               | PTT (seconds)                   | 30.0              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | -1                | -4               | Platelets (10 <sup>3</sup> /uL) | 175               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 168               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 174               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 170               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 189               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | -1                | -4               | Serum Lipase (U/L)              | 28.0              | N/A                         | N/A  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 1                 | 1                | Serum Lipase (U/L)           | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 8                 | 8                | Serum Lipase (U/L)           | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 29                | 29               | Serum Lipase (U/L)           | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 36                | 36               | Serum Lipase (U/L)           | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | -1                | -4               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 8                 | 8                | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 29                | 29               | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 36                | 36               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | -1                | -4               | WBC (10 <sup>3</sup> /uL)    | 5.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 4.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)    | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM012  | 100 µg (18-55 years) | MALE | 21          | 29                | 29               | WBC (10 <sup>3</sup> /uL)    | 5.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM012  | 100 µg (18-55 years) | MALE   | 21          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 5.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | -1                | -21              | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 1                 | 1                | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 8                 | 7                | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 29                | 28               | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 36                | 35               | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | -1                | -21              | Alkaline Phosphatase (U/L)     | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 8                 | 7                | Alkaline Phosphatase (U/L)     | 47                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 29                | 28               | Alkaline Phosphatase (U/L)     | 56                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 36                | 35               | Alkaline Phosphatase (U/L)     | 56                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | -1                | -21              | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 29                | 28               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 36                | 35               | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | -1                | -21              | Creatinine (mg/dL)               | 0.76              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 1                 | 1                | Creatinine (mg/dL)               | 0.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 8                 | 7                | Creatinine (mg/dL)               | 0.79              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 29                | 28               | Creatinine (mg/dL)               | 0.73              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 36                | 35               | Creatinine (mg/dL)               | 0.68              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | -1                | -21              | Hemoglobin (g/dL)                | 13.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology      | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 1                 | 1                | Hemoglobin (g/dL)               | 14.1              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 8                 | 7                | Hemoglobin (g/dL)               | 13.6 (Mild)       | NOT RELATED                 | Due to study procedure - phlebotomy       | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 29                | 28               | Hemoglobin (g/dL)               | 13.4 (Mild)       | NOT RELATED                 | Grade I due to study procedure phlebotomy | NA- NOT APPLICABLE                  | No                                  |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 36                | 35               | Hemoglobin (g/dL)               | 13.2 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy | NA- NOT APPLICABLE                  | No                                  |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | -1                | -21              | PT (seconds)                    | 9.9               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | -1                | -21              | PTT (seconds)                   | 29.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | -1                | -21              | Platelets (10 <sup>3</sup> /uL) | 291               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 275               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 282               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 29                | 28               | Platelets (10 <sup>3</sup> /uL) | 281               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 318               | N/A                         | N/A                                       | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | -1                | -21              | Serum Lipase (U/L)           | 64.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | -1                | -19              | Serum Lipase (U/L)           | 55.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 1                 | 1                | Serum Lipase (U/L)           | 47.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 8                 | 7                | Serum Lipase (U/L)           | 55.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 29                | 28               | Serum Lipase (U/L)           | 48.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 36                | 35               | Serum Lipase (U/L)           | 59.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | -1                | -21              | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 8                 | 7                | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 29                | 28               | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 36                | 35               | Total Bilirubin (mg/dL)      | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | -1                | -21              | WBC (10 <sup>3</sup> /uL)    | 5.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 5.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 5.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 29                | 28               | WBC (10 <sup>3</sup> /uL)      | 5.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM016  | 250 µg (18-55 years) | FEMALE | 24          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 5.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE   | 51          | -1                | -11              | Alanine Aminotransferase (U/L) | 33                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE   | 51          | 1                 | 1                | Alanine Aminotransferase (U/L) | 34                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE   | 51          | 8                 | 7                | Alanine Aminotransferase (U/L) | 27                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE   | 51          | 29                | 29               | Alanine Aminotransferase (U/L) | 35                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE   | 51          | 36                | 35               | Alanine Aminotransferase (U/L) | 34                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE   | 51          | 57                | 56               | Alanine Aminotransferase (U/L) | 31                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE   | 51          | -1                | -11              | Alkaline Phosphatase (U/L)     | 74                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE   | 51          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 72                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 69                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 29                | 29               | Alkaline Phosphatase (U/L)       | 73                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 36                | 35               | Alkaline Phosphatase (U/L)       | 70                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | -1                | -11              | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 29                | 29               | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 36                | 35               | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 57                | 56               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | -1                | -11              | Creatinine (mg/dL)               | 1.01              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 1                 | 1                | Creatinine (mg/dL)               | 1.12              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology      | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 8                 | 7                | Creatinine (mg/dL)              | 1.16              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 29                | 29               | Creatinine (mg/dL)              | 1.09              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 36                | 35               | Creatinine (mg/dL)              | 1.00              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | -1                | -11              | Hemoglobin (g/dL)               | 16.3              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 1                 | 1                | Hemoglobin (g/dL)               | 16.5              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 8                 | 7                | Hemoglobin (g/dL)               | 15.1 (Mild)       | NOT RELATED                 | Due to study procedure - phlebotomy       | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 29                | 29               | Hemoglobin (g/dL)               | 15.4 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 36                | 35               | Hemoglobin (g/dL)               | 14.7 (Moderate)   | RELATED                     | N/A                                       | NA- NOT APPLICABLE                  | No                                  |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | -1                | -11              | PT (seconds)                    | 10.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | -1                | -11              | PTT (seconds)                   | 30.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | -1                | -11              | Platelets (10 <sup>3</sup> /uL) | 267               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 266               | N/A                         | N/A                                       | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 266               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 241               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 253               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | -1                | -11              | Serum Lipase (U/L)              | 48.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 1                 | 1                | Serum Lipase (U/L)              | 62.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 8                 | 7                | Serum Lipase (U/L)              | 41.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 29                | 29               | Serum Lipase (U/L)              | 39.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 36                | 35               | Serum Lipase (U/L)              | 112.0 (Moderate)  | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 43                | 43               | Serum Lipase (U/L)              | 72.0 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 57                | 56               | Serum Lipase (U/L)              | 240.0 (Severe)    | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | -1                | -11              | Total Bilirubin (mg/dL)         | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 8                 | 7                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 29                | 29               | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 36                | 35               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 57                | 56               | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | -1                | -11              | WBC (10 <sup>3</sup> /uL)      | 5.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 5.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 6.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM020  | 250 µg (18-55 years) | MALE | 51          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 6.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | -1                | -7               | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 1                 | 1                | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 8                 | 7                | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 29                | 28               | Alanine Aminotransferase (U/L)   | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 36                | 36               | Alanine Aminotransferase (U/L)   | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | -1                | -7               | Alkaline Phosphatase (U/L)       | 62                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 60                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 62                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 29                | 28               | Alkaline Phosphatase (U/L)       | 65                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 36                | 36               | Alkaline Phosphatase (U/L)       | 66                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | -1                | -7               | Aspartate Aminotransferase (U/L) | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 29                | 28               | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology      | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 36                | 36               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | -1                | -7               | Creatinine (mg/dL)               | 1.05              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 1                 | 1                | Creatinine (mg/dL)               | 1.02              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 8                 | 7                | Creatinine (mg/dL)               | 1.03              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 29                | 28               | Creatinine (mg/dL)               | 0.94              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 36                | 36               | Creatinine (mg/dL)               | 1.08              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | -1                | -7               | Hemoglobin (g/dL)                | 16.1              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 1                 | 1                | Hemoglobin (g/dL)                | 14.8              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 8                 | 7                | Hemoglobin (g/dL)                | 14.1 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 29                | 28               | Hemoglobin (g/dL)                | 14.0 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy | NA- NOT APPLICABLE                  | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology       | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--|-------------------------------------|-------------------------------------|
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 36                | 36               | Hemoglobin (g/dL)               | 14.1 (Mild)       | NOT RELATED                 | Grade 1 -Due to study procedure-phlebotomy | NA- NOT APPLICABLE                  | No                                  |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | -1                | -7               | PT (seconds)                    | 11.5 (Mild)       | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | -1                | -4               | PT (seconds)                    | 10.6              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | -1                | -7               | PTT (seconds)                   | 36.0 (Mild)       | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | -1                | -4               | PTT (seconds)                   | 34.0 (Mild)       | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | -1                | -7               | Platelets (10 <sup>3</sup> /uL) | 304               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 267               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 283               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 29                | 28               | Platelets (10 <sup>3</sup> /uL) | 277               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 313               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | -1                | -7               | Serum Lipase (U/L)              | 61.0              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | -1                | -4               | Serum Lipase (U/L)              | 56.0              | N/A                         | N/A  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 1                 | 1                | Serum Lipase (U/L)           | 56.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 8                 | 7                | Serum Lipase (U/L)           | 50.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 29                | 28               | Serum Lipase (U/L)           | 43.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 36                | 36               | Serum Lipase (U/L)           | 54.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | -1                | -7               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 8                 | 7                | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 29                | 28               | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 36                | 36               | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | -1                | -7               | WBC (10 <sup>3</sup> /uL)    | 8.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 6.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)    | 6.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 29                | 28               | WBC (10 <sup>3</sup> /uL)    | 6.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM023  | 100 µg (56-70 years) | MALE | 69          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 6.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | -1                | -5               | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 1                 | 1                | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 8                 | 9                | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 29                | 30               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 36                | 38               | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | -1                | -5               | Alkaline Phosphatase (U/L)     | 63                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 68                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 8                 | 9                | Alkaline Phosphatase (U/L)     | 64                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 29                | 30               | Alkaline Phosphatase (U/L)     | 64                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 36                | 38               | Alkaline Phosphatase (U/L)     | 78                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | -1                | -5               | Aspartate Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 29                | 30               | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 36                | 38               | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | -1                | -5               | Creatinine (mg/dL)               | 0.82              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 1                 | 1                | Creatinine (mg/dL)               | 1.12              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 8                 | 9                | Creatinine (mg/dL)               | 0.96              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 29                | 30               | Creatinine (mg/dL)               | 0.91              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 36                | 38               | Creatinine (mg/dL)               | 0.92              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | -1                | -5               | Hemoglobin (g/dL)                | 15.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology       | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--|-------------------------------------|-------------------------------------|
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 1                 | 1                | Hemoglobin (g/dL)               | 15.1              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 8                 | 9                | Hemoglobin (g/dL)               | 14.7 (Mild)       | NOT RELATED                 | study procedures -phlebotomy               | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 29                | 30               | Hemoglobin (g/dL)               | 15.1              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 36                | 38               | Hemoglobin (g/dL)               | 14.8 (Mild)       | NOT RELATED                 | Grade 1- Due to study procedure phlebotomy | NA- NOT APPLICABLE                  | No                                  |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | -1                | -5               | PT (seconds)                    | 11.3              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | -1                | -5               | PTT (seconds)                   | 29.0              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | -1                | -5               | Platelets (10 <sup>3</sup> /uL) | 213               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 228               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 217               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 29                | 30               | Platelets (10 <sup>3</sup> /uL) | 203               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 36                | 38               | Platelets (10 <sup>3</sup> /uL) | 228               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | -1                | -5               | Serum Lipase (U/L)              | 12.0              | N/A                         | N/A  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 1                 | 1                | Serum Lipase (U/L)           | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 8                 | 9                | Serum Lipase (U/L)           | 11.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 29                | 30               | Serum Lipase (U/L)           | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 36                | 38               | Serum Lipase (U/L)           | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | -1                | -5               | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 8                 | 9                | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 29                | 30               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 36                | 38               | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | -1                | -5               | WBC (10 <sup>3</sup> /uL)    | 6.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 6.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)    | 6.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM024  | 100 µg (56-70 years) | MALE | 67          | 29                | 30               | WBC (10 <sup>3</sup> /uL)    | 5.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group       | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM024  | 100 µg<br>(56-70 years) | MALE   | 67          | 36                | 38               | WBC (10 <sup>3</sup> /uL)      | 9.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years)  | FEMALE | 65          | -1                | -5               | Alanine Aminotransferase (U/L) | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years)  | FEMALE | 65          | 1                 | 1                | Alanine Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years)  | FEMALE | 65          | 8                 | 8                | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years)  | FEMALE | 65          | 29                | 29               | Alanine Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years)  | FEMALE | 65          | 36                | 37               | Alanine Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years)  | FEMALE | 65          | -1                | -5               | Alkaline Phosphatase (U/L)     | 71                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years)  | FEMALE | 65          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 72                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years)  | FEMALE | 65          | 8                 | 8                | Alkaline Phosphatase (U/L)     | 72                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years)  | FEMALE | 65          | 29                | 29               | Alkaline Phosphatase (U/L)     | 78                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years)  | FEMALE | 65          | 36                | 37               | Alkaline Phosphatase (U/L)     | 79                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | -1                | -5               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | 29                | 29               | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | 36                | 37               | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | -1                | -5               | Creatinine (mg/dL)               | 0.64              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | 1                 | 1                | Creatinine (mg/dL)               | 0.73              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | 8                 | 8                | Creatinine (mg/dL)               | 0.69              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | 29                | 29               | Creatinine (mg/dL)               | 0.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | 36                | 37               | Creatinine (mg/dL)               | 0.72              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | -1                | -5               | Hemoglobin (g/dL)                | 14.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology      | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | 1                 | 1                | Hemoglobin (g/dL)               | 14.6              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | 8                 | 8                | Hemoglobin (g/dL)               | 13.5 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | 29                | 29               | Hemoglobin (g/dL)               | 13.9 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy | NA- NOT APPLICABLE                  | No                                  |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | 36                | 37               | Hemoglobin (g/dL)               | 13.7 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy | NA- NOT APPLICABLE                  | No                                  |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | -1                | -5               | PT (seconds)                    | 10.2              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | -1                | -5               | PTT (seconds)                   | 30.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | -1                | -5               | Platelets (10 <sup>3</sup> /uL) | 199               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 181               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 196               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 204               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 206               | N/A                         | N/A                                       | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM025  | 25 µg<br>(56-70 years) | FEMALE | 65          | -1                | -5               | Serum Lipase (U/L)           | 20.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years) | FEMALE | 65          | 1                 | 1                | Serum Lipase (U/L)           | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years) | FEMALE | 65          | 8                 | 8                | Serum Lipase (U/L)           | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years) | FEMALE | 65          | 29                | 29               | Serum Lipase (U/L)           | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years) | FEMALE | 65          | 36                | 37               | Serum Lipase (U/L)           | 38.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years) | FEMALE | 65          | -1                | -5               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years) | FEMALE | 65          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years) | FEMALE | 65          | 8                 | 8                | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years) | FEMALE | 65          | 29                | 29               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years) | FEMALE | 65          | 36                | 37               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years) | FEMALE | 65          | -1                | -5               | WBC (10 <sup>3</sup> /uL)    | 6.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years) | FEMALE | 65          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 5.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg<br>(56-70 years) | FEMALE | 65          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)    | 5.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 6.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM025  | 25 µg (56-70 years) | FEMALE | 65          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 6.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | -1                | -5               | Alanine Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 8                 | 8                | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 29                | 29               | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 36                | 37               | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | -1                | -5               | Alkaline Phosphatase (U/L)     | 57                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 8                 | 8                | Alkaline Phosphatase (U/L)     | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 29                | 29               | Alkaline Phosphatase (U/L)     | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 36                | 37               | Alkaline Phosphatase (U/L)       | 51                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | -1                | -5               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 29                | 29               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 36                | 37               | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | -1                | -5               | Creatinine (mg/dL)               | 0.75              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Creatinine (mg/dL)               | 0.77              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 8                 | 8                | Creatinine (mg/dL)               | 0.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 29                | 29               | Creatinine (mg/dL)               | 0.77              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 36                | 37               | Creatinine (mg/dL)               | 0.87              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology      | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | -1                | -5               | Hemoglobin (g/dL)               | 13.3              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Hemoglobin (g/dL)               | 12.9              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 8                 | 8                | Hemoglobin (g/dL)               | 11.7 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 29                | 29               | Hemoglobin (g/dL)               | 12.1 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy | NA- NOT APPLICABLE                  | No                                  |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 36                | 37               | Hemoglobin (g/dL)               | 11.4 (Mild)       | RELATED                     | N/A                                       | NA- NOT APPLICABLE                  | No                                  |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | -1                | -5               | PT (seconds)                    | 10.2              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | -1                | -5               | PTT (seconds)                   | 29.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | -1                | -5               | Platelets (10 <sup>3</sup> /uL) | 209               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 192               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 189               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 185               | N/A                         | N/A                                       | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM027  | 25 µg<br>(56-70 years) | FEMALE | 68          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 187               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg<br>(56-70 years) | FEMALE | 68          | -1                | -5               | Serum Lipase (U/L)              | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg<br>(56-70 years) | FEMALE | 68          | 1                 | 1                | Serum Lipase (U/L)              | 9.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg<br>(56-70 years) | FEMALE | 68          | 8                 | 8                | Serum Lipase (U/L)              | 12.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg<br>(56-70 years) | FEMALE | 68          | 29                | 29               | Serum Lipase (U/L)              | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg<br>(56-70 years) | FEMALE | 68          | 36                | 37               | Serum Lipase (U/L)              | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg<br>(56-70 years) | FEMALE | 68          | -1                | -5               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg<br>(56-70 years) | FEMALE | 68          | 1                 | 1                | Total Bilirubin (mg/dL)         | 1.1               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg<br>(56-70 years) | FEMALE | 68          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg<br>(56-70 years) | FEMALE | 68          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg<br>(56-70 years) | FEMALE | 68          | 36                | 37               | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg<br>(56-70 years) | FEMALE | 68          | -1                | -5               | WBC (10 <sup>3</sup> /uL)       | 6.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg<br>(56-70 years) | FEMALE | 68          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)       | 4.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 4.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM027  | 25 µg (56-70 years) | FEMALE | 68          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | -1                | -5               | Alanine Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 8                 | 8                | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 29                | 29               | Alanine Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 36                | 37               | Alanine Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | -1                | -5               | Alkaline Phosphatase (U/L)     | 105               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 103               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 8                 | 8                | Alkaline Phosphatase (U/L)     | 104               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 29                | 29               | Alkaline Phosphatase (U/L)       | 102               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 36                | 37               | Alkaline Phosphatase (U/L)       | 104               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | -1                | -5               | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 29                | 29               | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 36                | 37               | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | -1                | -5               | Creatinine (mg/dL)               | 0.74              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Creatinine (mg/dL)               | 0.66              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 8                 | 8                | Creatinine (mg/dL)               | 0.64              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 29                | 29               | Creatinine (mg/dL)               | 0.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology      | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 36                | 37               | Creatinine (mg/dL)              | 0.71              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | -1                | -5               | Hemoglobin (g/dL)               | 14.6              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Hemoglobin (g/dL)               | 14.8              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 8                 | 8                | Hemoglobin (g/dL)               | 14.8              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 29                | 29               | Hemoglobin (g/dL)               | 14.7 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy | NA- NOT APPLICABLE                  | No                                  |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 36                | 37               | Hemoglobin (g/dL)               | 14.5 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedures           | NA- NOT APPLICABLE                  | No                                  |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | -1                | -5               | PT (seconds)                    | 10.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | -1                | -5               | PTT (seconds)                   | 29.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | -1                | -5               | Platelets (10 <sup>3</sup> /uL) | 320               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 332               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 337               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg (56-70 years) | FEMALE | 68          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 352               | N/A                         | N/A                                       | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM029  | 25 µg<br>(56-70 years) | FEMALE | 68          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 361               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg<br>(56-70 years) | FEMALE | 68          | -1                | -5               | Serum Lipase (U/L)              | 34.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg<br>(56-70 years) | FEMALE | 68          | 1                 | 1                | Serum Lipase (U/L)              | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg<br>(56-70 years) | FEMALE | 68          | 8                 | 8                | Serum Lipase (U/L)              | 31.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg<br>(56-70 years) | FEMALE | 68          | 29                | 29               | Serum Lipase (U/L)              | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg<br>(56-70 years) | FEMALE | 68          | 36                | 37               | Serum Lipase (U/L)              | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg<br>(56-70 years) | FEMALE | 68          | -1                | -5               | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg<br>(56-70 years) | FEMALE | 68          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg<br>(56-70 years) | FEMALE | 68          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg<br>(56-70 years) | FEMALE | 68          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg<br>(56-70 years) | FEMALE | 68          | 36                | 37               | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg<br>(56-70 years) | FEMALE | 68          | -1                | -5               | WBC (10 <sup>3</sup> /uL)       | 8.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg<br>(56-70 years) | FEMALE | 68          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)       | 8.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM029  | 25 µg<br>(56-70 years) | FEMALE | 68          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 9.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg<br>(56-70 years) | FEMALE | 68          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 8.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM029  | 25 µg<br>(56-70 years) | FEMALE | 68          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 8.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | -1                | -5               | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 1                 | 1                | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 8                 | 8                | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 29                | 30               | Alanine Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 36                | 37               | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | -1                | -5               | Alkaline Phosphatase (U/L)     | 66                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 64                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 8                 | 8                | Alkaline Phosphatase (U/L)     | 68                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 29                | 30               | Alkaline Phosphatase (U/L)       | 66                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 36                | 37               | Alkaline Phosphatase (U/L)       | 75                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | -1                | -5               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 29                | 30               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 36                | 37               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | -1                | -5               | Creatinine (mg/dL)               | 0.77              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 1                 | 1                | Creatinine (mg/dL)               | 0.93              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 8                 | 8                | Creatinine (mg/dL)               | 0.92              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 29                | 30               | Creatinine (mg/dL)               | 0.89              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology      | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01EM030  | 25 µg (56-70 years) | FEMALE | 69          | 36                | 37               | Creatinine (mg/dL)              | 0.90              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg (56-70 years) | FEMALE | 69          | -1                | -5               | Hemoglobin (g/dL)               | 14.3              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg (56-70 years) | FEMALE | 69          | 1                 | 1                | Hemoglobin (g/dL)               | 14.7              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg (56-70 years) | FEMALE | 69          | 8                 | 8                | Hemoglobin (g/dL)               | 14.3 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM030  | 25 µg (56-70 years) | FEMALE | 69          | 29                | 30               | Hemoglobin (g/dL)               | 13.1 (Moderate)   | RELATED                     | N/A                                       | NA- NOT APPLICABLE                  | No                                  |
| CV01EM030  | 25 µg (56-70 years) | FEMALE | 69          | 36                | 37               | Hemoglobin (g/dL)               | 13.6 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy | NA- NOT APPLICABLE                  | No                                  |
| CV01EM030  | 25 µg (56-70 years) | FEMALE | 69          | -1                | -5               | PT (seconds)                    | 10.6              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg (56-70 years) | FEMALE | 69          | -1                | -5               | PTT (seconds)                   | 28.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg (56-70 years) | FEMALE | 69          | -1                | -5               | Platelets (10 <sup>3</sup> /uL) | 206               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg (56-70 years) | FEMALE | 69          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 221               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg (56-70 years) | FEMALE | 69          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 217               | N/A                         | N/A                                       | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 29                | 30               | Platelets (10 <sup>3</sup> /uL) | 221               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 246               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | -1                | -5               | Serum Lipase (U/L)              | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 1                 | 1                | Serum Lipase (U/L)              | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 8                 | 8                | Serum Lipase (U/L)              | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 29                | 30               | Serum Lipase (U/L)              | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 36                | 37               | Serum Lipase (U/L)              | 20.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | -1                | -5               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 29                | 30               | Total Bilirubin (mg/dL)         | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | 36                | 37               | Total Bilirubin (mg/dL)         | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg<br>(56-70 years) | FEMALE | 69          | -1                | -5               | WBC (10 <sup>3</sup> /uL)       | 5.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM030  | 25 µg (56-70 years)  | FEMALE | 69          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg (56-70 years)  | FEMALE | 69          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 6.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg (56-70 years)  | FEMALE | 69          | 29                | 30               | WBC (10 <sup>3</sup> /uL)      | 6.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM030  | 25 µg (56-70 years)  | FEMALE | 69          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 5.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | -1                | -5               | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 1                 | 1                | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 8                 | 7                | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 29                | 28               | Alanine Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 36                | 36               | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | -1                | -5               | Alkaline Phosphatase (U/L)     | 66                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 68                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 71                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 29                | 28               | Alkaline Phosphatase (U/L)       | 67                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 36                | 36               | Alkaline Phosphatase (U/L)       | 63                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | -1                | -5               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 29                | 28               | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 36                | 36               | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | -1                | -5               | Creatinine (mg/dL)               | 0.84              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 1                 | 1                | Creatinine (mg/dL)               | 0.85              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 8                 | 7                | Creatinine (mg/dL)               | 0.85              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology                                 | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--|-------------------------------------|-------------------------------------|
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 29                | 28               | Creatinine (mg/dL)           | 0.82              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 36                | 36               | Creatinine (mg/dL)           | 0.94              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | -1                | -5               | Hemoglobin (g/dL)            | 13.7              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 1                 | 1                | Hemoglobin (g/dL)            | 14.4              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 8                 | 7                | Hemoglobin (g/dL)            | 13.6 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy                            | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 29                | 28               | Hemoglobin (g/dL)            | 12.9 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy                            | NA- NOT APPLICABLE                  | No                                  |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 36                | 36               | Hemoglobin (g/dL)            | 12.5 (Moderate)   | RELATED                     | N/A  | NA- NOT APPLICABLE                  | No                                  |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 43                | 44               | Hemoglobin (g/dL)            | 12.4 (Moderate)   | RELATED                     | N/A  | NA- NOT APPLICABLE                  | No                                  |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 57                | 58               | Hemoglobin (g/dL)            | 12.4 (Moderate)   | RELATED                     | N/A  | NA- NOT APPLICABLE                  | No                                  |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 119               | 114              | Hemoglobin (g/dL)            | 12.3 (Severe)     | NOT RELATED                 | Grade 3. Due to study procedures Abnormally high baseline hemoglobin | NA- NOT APPLICABLE                  | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | -1                | -5               | PT (seconds)                    | 10.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | -1                | -5               | PTT (seconds)                   | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | -1                | -5               | Platelets (10 <sup>3</sup> /uL) | 216               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 199               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 216               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 29                | 28               | Platelets (10 <sup>3</sup> /uL) | 202               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 229               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | -1                | -5               | Serum Lipase (U/L)              | 57.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 1                 | 1                | Serum Lipase (U/L)              | 50.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 8                 | 7                | Serum Lipase (U/L)              | 50.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 29                | 28               | Serum Lipase (U/L)              | 62.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 36                | 36               | Serum Lipase (U/L)              | 72.0 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 43                | 44               | Serum Lipase (U/L)              | 68.0 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 57                | 58               | Serum Lipase (U/L)             | 70.0 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 119               | 114              | Serum Lipase (U/L)             | 62.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | -1                | -5               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 8                 | 7                | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 29                | 28               | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 36                | 36               | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | -1                | -5               | WBC (10 <sup>3</sup> /uL)      | 5.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 5.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 29                | 28               | WBC (10 <sup>3</sup> /uL)      | 5.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM032  | 100 µg (56-70 years) | FEMALE | 64          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 8.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | -1                | -5               | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 8                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 8                 | 8                | Alanine Aminotransferase (U/L)   | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 29                | 29               | Alanine Aminotransferase (U/L)   | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 36                | 36               | Alanine Aminotransferase (U/L)   | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | -1                | -5               | Alkaline Phosphatase (U/L)       | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 54                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 29                | 29               | Alkaline Phosphatase (U/L)       | 57                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 36                | 36               | Alkaline Phosphatase (U/L)       | 60                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | -1                | -5               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 29                | 29               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 36                | 36               | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | -1                | -5               | Creatinine (mg/dL)               | 0.79              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 1                 | 1                | Creatinine (mg/dL)               | 0.73              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 8                 | 8                | Creatinine (mg/dL)               | 0.87              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 29                | 29               | Creatinine (mg/dL)               | 0.75              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 36                | 36               | Creatinine (mg/dL)               | 0.77              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | -1                | -5               | Hemoglobin (g/dL)                | 13.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 1                 | 1                | Hemoglobin (g/dL)                | 13.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 8                 | 8                | Hemoglobin (g/dL)                | 12.5 (Mild)       | NOT RELATED                 | study procedures - phlebotomy        | NC- DOSE NOT CHANGED                | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology      | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 29                | 29               | Hemoglobin (g/dL)               | 13.0 (Mild)       | NOT RELATED                 | Grade 1, due to phlebotomy                | NA- NOT APPLICABLE                  | No                                  |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 36                | 36               | Hemoglobin (g/dL)               | 12.4 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy | NA- NOT APPLICABLE                  | No                                  |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | -1                | -5               | PT (seconds)                    | 10.3              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | -1                | -5               | PTT (seconds)                   | 31.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | -1                | -5               | Platelets (10 <sup>3</sup> /uL) | 371               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 355               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 370               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 352               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 379               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | -1                | -5               | Serum Lipase (U/L)              | 38.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 1                 | 1                | Serum Lipase (U/L)              | 38.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 8                 | 8                | Serum Lipase (U/L)              | 39.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 29                | 29               | Serum Lipase (U/L)             | 46.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 36                | 36               | Serum Lipase (U/L)             | 42.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | -1                | -5               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 8                 | 8                | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 29                | 29               | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 36                | 36               | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | -1                | -5               | WBC (10 <sup>3</sup> /uL)      | 6.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 6.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 7.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 7.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM033  | 100 µg (56-70 years) | FEMALE | 63          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 5.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE   | 66          | -1                | -5               | Alanine Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 8                 | 8                | Alanine Aminotransferase (U/L)   | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 29                | 29               | Alanine Aminotransferase (U/L)   | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 36                | 37               | Alanine Aminotransferase (U/L)   | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | -1                | -5               | Alkaline Phosphatase (U/L)       | 79                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 82                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 79                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 29                | 29               | Alkaline Phosphatase (U/L)       | 67                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 36                | 37               | Alkaline Phosphatase (U/L)       | 75                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | -1                | -5               | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 29                | 29               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 36                | 37               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | -1                | -5               | Creatinine (mg/dL)               | 1.08              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 1                 | 1                | Creatinine (mg/dL)               | 1.13              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 8                 | 8                | Creatinine (mg/dL)               | 1.19              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 29                | 29               | Creatinine (mg/dL)               | 1.17              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 36                | 37               | Creatinine (mg/dL)               | 1.25              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | -1                | -5               | Hemoglobin (g/dL)                | 15.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 1                 | 1                | Hemoglobin (g/dL)                | 15.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 8                 | 8                | Hemoglobin (g/dL)                | 15.2 (Mild)       | NOT RELATED                 | study procedure phlebotomy           | NC- DOSE NOT CHANGED                | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology          | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 29                | 29               | Hemoglobin (g/dL)               | 14.8 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy     | NA- NOT APPLICABLE                  | No                                  |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 36                | 37               | Hemoglobin (g/dL)               | 14.7 (Mild)       | NOT RELATED                 | Grade 1- due to study procedure - phlebotomy. | NA- NOT APPLICABLE                  | No                                  |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | -1                | -5               | PT (seconds)                    | 10.3              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | -1                | -5               | PTT (seconds)                   | 28.0              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | -1                | -5               | Platelets (10 <sup>3</sup> /uL) | 267               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 267               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 256               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 250               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 289               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | -1                | -5               | Serum Lipase (U/L)              | 48.0              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 1                 | 1                | Serum Lipase (U/L)              | 56.0              | N/A                         | N/A   | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 8                 | 8                | Serum Lipase (U/L)           | 65.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 29                | 29               | Serum Lipase (U/L)           | 48.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 36                | 37               | Serum Lipase (U/L)           | 54.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | -1                | -5               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 8                 | 8                | Total Bilirubin (mg/dL)      | 1.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 29                | 29               | Total Bilirubin (mg/dL)      | 1.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 36                | 37               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | -1                | -5               | WBC (10 <sup>3</sup> /uL)    | 7.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 6.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)    | 5.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 29                | 29               | WBC (10 <sup>3</sup> /uL)    | 4.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM039  | 100 µg (56-70 years) | MALE | 66          | 36                | 37               | WBC (10 <sup>3</sup> /uL)    | 5.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | -1                | -3               | Alanine Aminotransferase (U/L)   | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 8                 | 9                | Alanine Aminotransferase (U/L)   | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 29                | 30               | Alanine Aminotransferase (U/L)   | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 36                | 37               | Alanine Aminotransferase (U/L)   | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | -1                | -3               | Alkaline Phosphatase (U/L)       | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 8                 | 9                | Alkaline Phosphatase (U/L)       | 54                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 29                | 30               | Alkaline Phosphatase (U/L)       | 47                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 36                | 37               | Alkaline Phosphatase (U/L)       | 56                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | -1                | -3               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 29                | 30               | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 36                | 37               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | -1                | -3               | Creatinine (mg/dL)               | 0.65              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 1                 | 1                | Creatinine (mg/dL)               | 0.66              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 8                 | 9                | Creatinine (mg/dL)               | 0.68              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 29                | 30               | Creatinine (mg/dL)               | 0.64              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 36                | 37               | Creatinine (mg/dL)               | 0.68              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | -1                | -3               | Hemoglobin (g/dL)                | 13.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 1                 | 1                | Hemoglobin (g/dL)                | 12.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology      | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 8                 | 9                | Hemoglobin (g/dL)               | 12.6 (Mild)       | NOT RELATED                 | study procedures -phlebotomy              | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 29                | 30               | Hemoglobin (g/dL)               | 12.2 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy | NA- NOT APPLICABLE                  | No                                  |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 36                | 37               | Hemoglobin (g/dL)               | 13.3              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | -1                | -3               | PT (seconds)                    | 10.3              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | -1                | -3               | PTT (seconds)                   | 30.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | -1                | -3               | Platelets (10 <sup>3</sup> /uL) | 361               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 395               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 388               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 29                | 30               | Platelets (10 <sup>3</sup> /uL) | 350               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 379               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | -1                | -3               | Serum Lipase (U/L)              | 28.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg (56-70 years) | FEMALE | 60          | 1                 | 1                | Serum Lipase (U/L)              | 32.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM041  | 25 µg<br>(56-70 years) | FEMALE | 60          | 8                 | 9                | Serum Lipase (U/L)           | 37.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg<br>(56-70 years) | FEMALE | 60          | 29                | 30               | Serum Lipase (U/L)           | 43.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg<br>(56-70 years) | FEMALE | 60          | 36                | 37               | Serum Lipase (U/L)           | 33.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg<br>(56-70 years) | FEMALE | 60          | -1                | -3               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg<br>(56-70 years) | FEMALE | 60          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg<br>(56-70 years) | FEMALE | 60          | 8                 | 9                | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg<br>(56-70 years) | FEMALE | 60          | 29                | 30               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg<br>(56-70 years) | FEMALE | 60          | 36                | 37               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg<br>(56-70 years) | FEMALE | 60          | -1                | -3               | WBC (10 <sup>3</sup> /uL)    | 5.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg<br>(56-70 years) | FEMALE | 60          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 6.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg<br>(56-70 years) | FEMALE | 60          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)    | 6.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg<br>(56-70 years) | FEMALE | 60          | 29                | 30               | WBC (10 <sup>3</sup> /uL)    | 5.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM041  | 25 µg<br>(56-70 years) | FEMALE | 60          | 36                | 37               | WBC (10 <sup>3</sup> /uL)    | 7.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | -1                | -7               | Alanine Aminotransferase (U/L)   | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 8                 | 7                | Alanine Aminotransferase (U/L)   | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 29                | 28               | Alanine Aminotransferase (U/L)   | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 36                | 35               | Alanine Aminotransferase (U/L)   | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | -1                | -7               | Alkaline Phosphatase (U/L)       | 44                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 42                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 29                | 28               | Alkaline Phosphatase (U/L)       | 44                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 36                | 35               | Alkaline Phosphatase (U/L)       | 41                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | -1                | -7               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 29                | 28               | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 36                | 35               | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | -1                | -7               | Creatinine (mg/dL)               | 0.69              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Creatinine (mg/dL)               | 0.61              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 8                 | 7                | Creatinine (mg/dL)               | 0.83              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 29                | 28               | Creatinine (mg/dL)               | 0.67              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 36                | 35               | Creatinine (mg/dL)               | 0.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | -1                | -7               | Hemoglobin (g/dL)                | 13.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Hemoglobin (g/dL)                | 13.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology          | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 8                 | 7                | Hemoglobin (g/dL)               | 12.5 (Mild)       | NOT RELATED                 | Due to study procedure phlebotomy             | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 29                | 28               | Hemoglobin (g/dL)               | 12.5 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy     | NA- NOT APPLICABLE                  | No                                  |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 36                | 35               | Hemoglobin (g/dL)               | 12.1 (Mild)       | NOT RELATED                 | Grade 1- due to study procedure - phlebotomy. | NA- NOT APPLICABLE                  | No                                  |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | -1                | -7               | PT (seconds)                    | 10.7              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | -1                | -7               | PTT (seconds)                   | 30.0              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | -1                | -7               | Platelets (10 <sup>3</sup> /uL) | 350               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 352               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 346               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 29                | 28               | Platelets (10 <sup>3</sup> /uL) | 358               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 356               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | -1                | -7               | Serum Lipase (U/L)              | 30.0              | N/A                         | N/A   | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Serum Lipase (U/L)           | 42.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 8                 | 7                | Serum Lipase (U/L)           | 45.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 29                | 28               | Serum Lipase (U/L)           | 45.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 36                | 35               | Serum Lipase (U/L)           | 36.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | -1                | -7               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 8                 | 7                | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 29                | 28               | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 36                | 35               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | -1                | -7               | WBC (10 <sup>3</sup> /uL)    | 5.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 6.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)    | 6.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM045  | 100 µg (56-70 years) | FEMALE | 68          | 29                | 28               | WBC (10 <sup>3</sup> /uL)    | 4.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group       | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM045  | 100 µg<br>(56-70 years) | FEMALE | 68          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 5.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg<br>(18-55 years)  | MALE   | 42          | -1                | -2               | Alanine Aminotransferase (U/L) | 27                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg<br>(18-55 years)  | MALE   | 42          | 1                 | 1                | Alanine Aminotransferase (U/L) | 29                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg<br>(18-55 years)  | MALE   | 42          | 8                 | 7                | Alanine Aminotransferase (U/L) | 31                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg<br>(18-55 years)  | MALE   | 42          | 29                | 29               | Alanine Aminotransferase (U/L) | 35                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg<br>(18-55 years)  | MALE   | 42          | 36                | 35               | Alanine Aminotransferase (U/L) | 37                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg<br>(18-55 years)  | MALE   | 42          | -1                | -2               | Alkaline Phosphatase (U/L)     | 63                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg<br>(18-55 years)  | MALE   | 42          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 73                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg<br>(18-55 years)  | MALE   | 42          | 8                 | 7                | Alkaline Phosphatase (U/L)     | 73                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg<br>(18-55 years)  | MALE   | 42          | 29                | 29               | Alkaline Phosphatase (U/L)     | 64                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg<br>(18-55 years)  | MALE   | 42          | 36                | 35               | Alkaline Phosphatase (U/L)     | 69                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | -1                | -2               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 29                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 29                | 29               | Aspartate Aminotransferase (U/L) | 32                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 36                | 35               | Aspartate Aminotransferase (U/L) | 33                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | -1                | -2               | Creatinine (mg/dL)               | 0.95              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 1                 | 1                | Creatinine (mg/dL)               | 0.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 8                 | 7                | Creatinine (mg/dL)               | 1.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 29                | 29               | Creatinine (mg/dL)               | 1.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 36                | 35               | Creatinine (mg/dL)               | 0.91              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | -1                | -2               | Hemoglobin (g/dL)                | 15.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology      | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 1                 | 1                | Hemoglobin (g/dL)               | 15.3              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 8                 | 7                | Hemoglobin (g/dL)               | 14.9 (Mild)       | NOT RELATED                 | Grade 1 = phlebotomy                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 29                | 29               | Hemoglobin (g/dL)               | 15.2 (Mild)       | NOT RELATED                 | Due to study procedure - phlebotomy       | NA- NOT APPLICABLE                  | No                                  |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 36                | 35               | Hemoglobin (g/dL)               | 14.8 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy | NA- NOT APPLICABLE                  | No                                  |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | -1                | -2               | PT (seconds)                    | 10.6              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | -1                | -2               | PTT (seconds)                   | 31.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | -1                | -2               | Platelets (10 <sup>3</sup> /uL) | 220               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 241               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 217               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 224               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 231               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | -1                | -2               | Serum Lipase (U/L)              | 16.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 1                 | 1                | Serum Lipase (U/L)           | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 8                 | 7                | Serum Lipase (U/L)           | 12.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 29                | 29               | Serum Lipase (U/L)           | 13.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 36                | 35               | Serum Lipase (U/L)           | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | -1                | -2               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 8                 | 7                | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 29                | 29               | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 36                | 35               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | -1                | -2               | WBC (10 <sup>3</sup> /uL)    | 6.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 6.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)    | 6.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 29                | 29               | WBC (10 <sup>3</sup> /uL)    | 5.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM049  | 50 µg (18-55 years) | MALE | 42          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 6.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | -1                | -2               | Alanine Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 1                 | 1                | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 8                 | 8                | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 29                | 27               | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 36                | 35               | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | -1                | -2               | Alkaline Phosphatase (U/L)     | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 64                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 8                 | 8                | Alkaline Phosphatase (U/L)     | 63                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 29                | 27               | Alkaline Phosphatase (U/L)     | 61                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 36                | 35               | Alkaline Phosphatase (U/L)     | 66                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | -1                | -2               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 29                | 27               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 36                | 35               | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | -1                | -2               | Creatinine (mg/dL)               | 0.95              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 1                 | 1                | Creatinine (mg/dL)               | 0.83              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 8                 | 8                | Creatinine (mg/dL)               | 0.89              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 29                | 27               | Creatinine (mg/dL)               | 1.06              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 36                | 35               | Creatinine (mg/dL)               | 0.89              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | -1                | -2               | Hemoglobin (g/dL)                | 14.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology      | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 1                 | 1                | Hemoglobin (g/dL)               | 15.4              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 8                 | 8                | Hemoglobin (g/dL)               | 14.8 (Mild)       | NOT RELATED                 | Grade 1 - phlebotomy                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 29                | 27               | Hemoglobin (g/dL)               | 14.6 (Mild)       | NOT RELATED                 | Study procedure phlebotomy                | NA- NOT APPLICABLE                  | No                                  |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 36                | 35               | Hemoglobin (g/dL)               | 14.8 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure Phlebotomy | NA- NOT APPLICABLE                  | No                                  |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | -1                | -2               | PT (seconds)                    | 11.1              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | -1                | -2               | PTT (seconds)                   | 30.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | -1                | -2               | Platelets (10 <sup>3</sup> /uL) | 273               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 273               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 270               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 243               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 297               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg (18-55 years) | MALE | 50          | -1                | -2               | Serum Lipase (U/L)              | 36.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM051  | 50 µg<br>(18-55 years) | MALE | 50          | 1                 | 1                | Serum Lipase (U/L)           | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg<br>(18-55 years) | MALE | 50          | 8                 | 8                | Serum Lipase (U/L)           | 36.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg<br>(18-55 years) | MALE | 50          | 29                | 27               | Serum Lipase (U/L)           | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg<br>(18-55 years) | MALE | 50          | 36                | 35               | Serum Lipase (U/L)           | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg<br>(18-55 years) | MALE | 50          | -1                | -2               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg<br>(18-55 years) | MALE | 50          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg<br>(18-55 years) | MALE | 50          | 8                 | 8                | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg<br>(18-55 years) | MALE | 50          | 29                | 27               | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg<br>(18-55 years) | MALE | 50          | 36                | 35               | Total Bilirubin (mg/dL)      | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg<br>(18-55 years) | MALE | 50          | -1                | -2               | WBC (10 <sup>3</sup> /uL)    | 6.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg<br>(18-55 years) | MALE | 50          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 8.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg<br>(18-55 years) | MALE | 50          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)    | 8.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM051  | 50 µg<br>(18-55 years) | MALE | 50          | 29                | 27               | WBC (10 <sup>3</sup> /uL)    | 6.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM051  | 50 µg<br>(18-55 years) | MALE   | 50          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 7.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg<br>(18-55 years) | FEMALE | 27          | -1                | -2               | Alanine Aminotransferase (U/L) | 7                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg<br>(18-55 years) | FEMALE | 27          | 1                 | 1                | Alanine Aminotransferase (U/L) | 8                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg<br>(18-55 years) | FEMALE | 27          | 8                 | 9                | Alanine Aminotransferase (U/L) | 7                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg<br>(18-55 years) | FEMALE | 27          | 29                | 27               | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg<br>(18-55 years) | FEMALE | 27          | 36                | 35               | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg<br>(18-55 years) | FEMALE | 27          | -1                | -2               | Alkaline Phosphatase (U/L)     | 46                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg<br>(18-55 years) | FEMALE | 27          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 40                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg<br>(18-55 years) | FEMALE | 27          | 8                 | 9                | Alkaline Phosphatase (U/L)     | 50                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg<br>(18-55 years) | FEMALE | 27          | 29                | 27               | Alkaline Phosphatase (U/L)     | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg<br>(18-55 years) | FEMALE | 27          | 36                | 35               | Alkaline Phosphatase (U/L)     | 45                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | -1                | -2               | Aspartate Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 29                | 27               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 36                | 35               | Aspartate Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | -1                | -2               | Creatinine (mg/dL)               | 0.72              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 1                 | 1                | Creatinine (mg/dL)               | 0.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 8                 | 9                | Creatinine (mg/dL)               | 0.64              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 29                | 27               | Creatinine (mg/dL)               | 0.63              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 36                | 35               | Creatinine (mg/dL)               | 0.67              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | -1                | -2               | Hemoglobin (g/dL)                | 14.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology      | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 1                 | 1                | Hemoglobin (g/dL)               | 13.5              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 8                 | 9                | Hemoglobin (g/dL)               | 14.9              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 29                | 27               | Hemoglobin (g/dL)               | 13.9              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 36                | 35               | Hemoglobin (g/dL)               | 13.4 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy | NA- NOT APPLICABLE                  | No                                  |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | -1                | -2               | PT (seconds)                    | 10.5              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | -1                | -2               | PTT (seconds)                   | 30.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | -1                | -2               | Platelets (10 <sup>3</sup> /uL) | 240               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 227               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 256               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 258               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 227               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | -1                | -2               | Serum Lipase (U/L)              | 19.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 1                 | 1                | Serum Lipase (U/L)           | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 8                 | 9                | Serum Lipase (U/L)           | 60.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 29                | 27               | Serum Lipase (U/L)           | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 36                | 35               | Serum Lipase (U/L)           | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | -1                | -2               | Total Bilirubin (mg/dL)      | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 8                 | 9                | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 29                | 27               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 36                | 35               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | -1                | -2               | WBC (10 <sup>3</sup> /uL)    | 9.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 8.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)    | 5.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM053  | 50 µg (18-55 years) | FEMALE | 27          | 29                | 27               | WBC (10 <sup>3</sup> /uL)    | 7.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM053  | 50 µg<br>(18-55 years) | FEMALE | 27          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 5.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg<br>(18-55 years) | FEMALE | 54          | -1                | -2               | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg<br>(18-55 years) | FEMALE | 54          | 1                 | 1                | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg<br>(18-55 years) | FEMALE | 54          | 8                 | 9                | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg<br>(18-55 years) | FEMALE | 54          | 29                | 27               | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg<br>(18-55 years) | FEMALE | 54          | 36                | 35               | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg<br>(18-55 years) | FEMALE | 54          | -1                | -2               | Alkaline Phosphatase (U/L)     | 70                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg<br>(18-55 years) | FEMALE | 54          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 68                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg<br>(18-55 years) | FEMALE | 54          | 8                 | 9                | Alkaline Phosphatase (U/L)     | 76                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg<br>(18-55 years) | FEMALE | 54          | 29                | 27               | Alkaline Phosphatase (U/L)     | 73                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg<br>(18-55 years) | FEMALE | 54          | 36                | 35               | Alkaline Phosphatase (U/L)     | 77                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | -1                | -2               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 29                | 27               | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 36                | 35               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | -1                | -2               | Creatinine (mg/dL)               | 0.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 1                 | 1                | Creatinine (mg/dL)               | 0.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 8                 | 9                | Creatinine (mg/dL)               | 0.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 29                | 27               | Creatinine (mg/dL)               | 0.93              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 36                | 35               | Creatinine (mg/dL)               | 0.78              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | -1                | -2               | Hemoglobin (g/dL)                | 13.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology      | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 1                 | 1                | Hemoglobin (g/dL)               | 13.3              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 8                 | 9                | Hemoglobin (g/dL)               | 12.9 (Mild)       | NOT RELATED                 | Grade 1 Due to study procedure phlebotomy | NC- DOSE NOT CHANGED                | No                                  |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 29                | 27               | Hemoglobin (g/dL)               | 13.0 (Mild)       | NOT RELATED                 | study procedure phlebotomy                | NA- NOT APPLICABLE                  | No                                  |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 36                | 35               | Hemoglobin (g/dL)               | 13.4              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | -1                | -2               | PT (seconds)                    | 10.2              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | -1                | -2               | PTT (seconds)                   | 27.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | -1                | -2               | Platelets (10 <sup>3</sup> /uL) | 220               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 221               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 227               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 207               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 234               | N/A                         | N/A                                       | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | -1                | -2               | Serum Lipase (U/L)              | 51.0              | N/A                         | N/A                                       | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 1                 | 1                | Serum Lipase (U/L)           | 118.0 (Moderate)  | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 8                 | 9                | Serum Lipase (U/L)           | 44.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 29                | 27               | Serum Lipase (U/L)           | 57.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 36                | 35               | Serum Lipase (U/L)           | 50.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | -1                | -2               | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 8                 | 9                | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 29                | 27               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 36                | 35               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | -1                | -2               | WBC (10 <sup>3</sup> /uL)    | 6.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 6.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)    | 6.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01EM054  | 50 µg (18-55 years) | FEMALE | 54          | 29                | 27               | WBC (10 <sup>3</sup> /uL)    | 6.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group       | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01EM054  | 50 µg<br>(18-55 years)  | FEMALE | 54          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 6.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg<br>(18-55 years) | MALE   | 22          | -1                | -4               | Alanine Aminotransferase (U/L) | 35                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg<br>(18-55 years) | MALE   | 22          | 1                 | 1                | Alanine Aminotransferase (U/L) | 34                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg<br>(18-55 years) | MALE   | 22          | 8                 | 9                | Alanine Aminotransferase (U/L) | 39                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg<br>(18-55 years) | MALE   | 22          | 29                | 29               | Alanine Aminotransferase (U/L) | 52 (Mild)         | NOT RELATED                 | Related to Alcohol                   | NA- NOT APPLICABLE                  | No                                  |
| CV01HC003  | 100 µg<br>(18-55 years) | MALE   | 22          | 36                | 35               | Alanine Aminotransferase (U/L) | 37                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg<br>(18-55 years) | MALE   | 22          | -1                | -4               | Alkaline Phosphatase (U/L)     | 86                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg<br>(18-55 years) | MALE   | 22          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 76                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg<br>(18-55 years) | MALE   | 22          | 8                 | 9                | Alkaline Phosphatase (U/L)     | 90                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg<br>(18-55 years) | MALE   | 22          | 29                | 29               | Alkaline Phosphatase (U/L)     | 77                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg<br>(18-55 years) | MALE   | 22          | 36                | 35               | Alkaline Phosphatase (U/L)     | 81                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | -1                | -4               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 29                | 29               | Aspartate Aminotransferase (U/L) | 27                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 36                | 35               | Aspartate Aminotransferase (U/L) | 26                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | -1                | -4               | Creatinine (mg/dL)               | 0.82              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 1                 | 1                | Creatinine (mg/dL)               | 0.92              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 8                 | 9                | Creatinine (mg/dL)               | 0.95              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 29                | 29               | Creatinine (mg/dL)               | 0.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 36                | 35               | Creatinine (mg/dL)               | 0.97              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | -1                | -4               | Hemoglobin (g/dL)                | 14.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 1                 | 1                | Hemoglobin (g/dL)               | 13.4 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 8                 | 9                | Hemoglobin (g/dL)               | 14.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 29                | 29               | Hemoglobin (g/dL)               | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 36                | 35               | Hemoglobin (g/dL)               | 14.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | -1                | -4               | PT (seconds)                    | 9.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | -1                | -4               | PTT (seconds)                   | 33.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | -1                | -4               | Platelets (10 <sup>3</sup> /uL) | 367               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 321               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 379               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 367               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 345               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | -1                | -4               | Serum Lipase (U/L)              | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 1                 | 1                | Serum Lipase (U/L)              | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 8                 | 9                | Serum Lipase (U/L)           | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 29                | 29               | Serum Lipase (U/L)           | 33.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 36                | 35               | Serum Lipase (U/L)           | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | -1                | -4               | Total Bilirubin (mg/dL)      | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 8                 | 9                | Total Bilirubin (mg/dL)      | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 29                | 29               | Total Bilirubin (mg/dL)      | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 36                | 35               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | -1                | -4               | WBC (10 <sup>3</sup> /uL)    | 6.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 5.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)    | 5.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 29                | 29               | WBC (10 <sup>3</sup> /uL)    | 6.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC003  | 100 µg (18-55 years) | MALE | 22          | 36                | 35               | WBC (10 <sup>3</sup> /uL)    | 5.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | -1                | -4               | Alanine Aminotransferase (U/L)   | 34                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 31                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 8                 | 8                | Alanine Aminotransferase (U/L)   | 88 (Mild)         | NOT RELATED                 | subject confirmed alcohol use        | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 29                | 29               | Alanine Aminotransferase (U/L)   | 39                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 36                | 36               | Alanine Aminotransferase (U/L)   | 31                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | -1                | -4               | Alkaline Phosphatase (U/L)       | 71                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 91                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 29                | 29               | Alkaline Phosphatase (U/L)       | 73                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 36                | 36               | Alkaline Phosphatase (U/L)       | 64                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | -1                | -4               | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 29                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 41                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 29                | 29               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 36                | 36               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | -1                | -4               | Creatinine (mg/dL)               | 1.18              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 1                 | 1                | Creatinine (mg/dL)               | 1.17              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 8                 | 8                | Creatinine (mg/dL)               | 1.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 29                | 29               | Creatinine (mg/dL)               | 1.14              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 36                | 36               | Creatinine (mg/dL)               | 1.26              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | -1                | -4               | Hemoglobin (g/dL)                | 15.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 1                 | 1                | Hemoglobin (g/dL)                | 13.1 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 8                 | 8                | Hemoglobin (g/dL)               | 14.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 29                | 29               | Hemoglobin (g/dL)               | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 36                | 36               | Hemoglobin (g/dL)               | 14.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | -1                | -4               | PT (seconds)                    | 10.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | -1                | -4               | PTT (seconds)                   | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | -1                | -4               | Platelets (10 <sup>3</sup> /uL) | 359               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 321               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 328               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 302               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 348               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | -1                | -4               | Serum Lipase (U/L)              | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 1                 | 1                | Serum Lipase (U/L)              | 31.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 8                 | 8                | Serum Lipase (U/L)              | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 29                | 29               | Serum Lipase (U/L)             | 41.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 36                | 36               | Serum Lipase (U/L)             | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | -1                | -4               | Total Bilirubin (mg/dL)        | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 8                 | 8                | Total Bilirubin (mg/dL)        | 1.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 29                | 29               | Total Bilirubin (mg/dL)        | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 36                | 36               | Total Bilirubin (mg/dL)        | 1.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | -1                | -4               | WBC (10 <sup>3</sup> /uL)      | 8.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 7.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 7.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 6.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC004  | 100 µg (18-55 years) | MALE | 34          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 6.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | -1                | -3               | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 8                 | 8                | Alanine Aminotransferase (U/L)   | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 29                | 28               | Alanine Aminotransferase (U/L)   | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 36                | 35               | Alanine Aminotransferase (U/L)   | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | -1                | -3               | Alkaline Phosphatase (U/L)       | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 42                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 47                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 29                | 28               | Alkaline Phosphatase (U/L)       | 35                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 36                | 35               | Alkaline Phosphatase (U/L)       | 39                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | -1                | -3               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 29                | 28               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 36                | 35               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | -1                | -3               | Creatinine (mg/dL)               | 0.82              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Creatinine (mg/dL)               | 0.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 8                 | 8                | Creatinine (mg/dL)               | 0.76              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 29                | 28               | Creatinine (mg/dL)               | 0.73              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 36                | 35               | Creatinine (mg/dL)               | 0.72              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | -1                | -3               | Hemoglobin (g/dL)                | 15.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Hemoglobin (g/dL)                | 14.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 8                 | 8                | Hemoglobin (g/dL)                | 14.4 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 29                | 28               | Hemoglobin (g/dL)                | 14.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 36                | 35               | Hemoglobin (g/dL)               | 14.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | -1                | -3               | PT (seconds)                    | 10.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | -1                | -3               | PTT (seconds)                   | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | -1                | -3               | Platelets (10 <sup>3</sup> /uL) | 265               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 245               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 260               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 29                | 28               | Platelets (10 <sup>3</sup> /uL) | 235               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 267               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | -1                | -3               | Serum Lipase (U/L)              | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 1                 | 1                | Serum Lipase (U/L)              | 11.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 8                 | 8                | Serum Lipase (U/L)              | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 29                | 28               | Serum Lipase (U/L)              | 11.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE | 32          | 36                | 35               | Serum Lipase (U/L)              | 11.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC007  | 100 µg (18-55 years) | MALE   | 32          | -1                | -3               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE   | 32          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE   | 32          | 8                 | 8                | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE   | 32          | 29                | 28               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE   | 32          | 36                | 35               | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE   | 32          | -1                | -3               | WBC (10 <sup>3</sup> /uL)      | 6.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE   | 32          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 4.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE   | 32          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE   | 32          | 29                | 28               | WBC (10 <sup>3</sup> /uL)      | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC007  | 100 µg (18-55 years) | MALE   | 32          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 5.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | -1                | -5               | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 1                 | 1                | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 8                 | 8                | Alanine Aminotransferase (U/L)   | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 29                | 29               | Alanine Aminotransferase (U/L)   | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 36                | 36               | Alanine Aminotransferase (U/L)   | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | -1                | -5               | Alkaline Phosphatase (U/L)       | 45                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 43                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 42                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 29                | 29               | Alkaline Phosphatase (U/L)       | 45                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 36                | 36               | Alkaline Phosphatase (U/L)       | 46                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | -1                | -5               | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 29                | 29               | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 36                | 36               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | -1                | -5               | Creatinine (mg/dL)               | 0.69              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 1                 | 1                | Creatinine (mg/dL)               | 0.64              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 8                 | 8                | Creatinine (mg/dL)               | 0.65              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 29                | 29               | Creatinine (mg/dL)               | 0.64              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 36                | 36               | Creatinine (mg/dL)               | 0.75              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | -1                | -5               | Hemoglobin (g/dL)                | 14.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 1                 | 1                | Hemoglobin (g/dL)                | 13.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 8                 | 8                | Hemoglobin (g/dL)                | 12.4 (Mild)       | NOT RELATED                 | phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 29                | 29               | Hemoglobin (g/dL)                | 12.1 (Mild)       | NOT RELATED                 | Normal variation                     | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 36                | 36               | Hemoglobin (g/dL)                | 13.0 (Mild)       | NOT RELATED                 | normal lab variation                 | NA- NOT APPLICABLE                  | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | -1                | -5               | PT (seconds)                    | 11.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | -1                | -5               | PTT (seconds)                   | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | -1                | -5               | Platelets (10 <sup>3</sup> /uL) | 247               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 222               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 217               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 211               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 249               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | -1                | -5               | Serum Lipase (U/L)              | 12.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 1                 | 1                | Serum Lipase (U/L)              | 10.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 8                 | 8                | Serum Lipase (U/L)              | 12.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 29                | 29               | Serum Lipase (U/L)              | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 36                | 36               | Serum Lipase (U/L)              | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | -1                | -5               | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 8                 | 8                | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 29                | 29               | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 36                | 36               | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | -1                | -5               | WBC (10 <sup>3</sup> /uL)      | 5.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 4.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 5.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC008  | 100 µg (18-55 years) | FEMALE | 26          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 4.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | -1                | -15              | Alanine Aminotransferase (U/L) | 7                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 1                 | 1                | Alanine Aminotransferase (U/L) | 7                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 8                 | 7                | Alanine Aminotransferase (U/L) | 7                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 29                | 29               | Alanine Aminotransferase (U/L)   | 7                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 36                | 36               | Alanine Aminotransferase (U/L)   | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | -1                | -15              | Alkaline Phosphatase (U/L)       | 50                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 47                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 29                | 29               | Alkaline Phosphatase (U/L)       | 51                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 36                | 36               | Alkaline Phosphatase (U/L)       | 50                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | -1                | -15              | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 29                | 29               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 36                | 36               | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | -1                | -15              | Creatinine (mg/dL)               | 0.72              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 1                 | 1                | Creatinine (mg/dL)               | 0.77              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 8                 | 7                | Creatinine (mg/dL)               | 0.73              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 29                | 29               | Creatinine (mg/dL)               | 0.75              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 36                | 36               | Creatinine (mg/dL)               | 0.77              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | -1                | -15              | Hemoglobin (g/dL)                | 12.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 1                 | 1                | Hemoglobin (g/dL)                | 12.0 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 8                 | 7                | Hemoglobin (g/dL)                | 12.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 29                | 29               | Hemoglobin (g/dL)                | 12.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 36                | 36               | Hemoglobin (g/dL)                | 12.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | -1                | -15              | PT (seconds)                     | 10.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | -1                | -15              | PTT (seconds)                    | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | -1                | -15              | Platelets (10 <sup>3</sup> /uL) | 354               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 373               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 420               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 415               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 407               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | -1                | -15              | Serum Lipase (U/L)              | 20.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 1                 | 1                | Serum Lipase (U/L)              | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 8                 | 7                | Serum Lipase (U/L)              | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 29                | 29               | Serum Lipase (U/L)              | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 36                | 36               | Serum Lipase (U/L)              | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | -1                | -15              | Total Bilirubin (mg/dL)         | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 8                 | 7                | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 29                | 29               | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 36                | 36               | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | -1                | -15              | WBC (10 <sup>3</sup> /uL)      | 6.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 6.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 5.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC012  | 250 µg (18-55 years) | FEMALE | 41          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 5.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | -1                | -15              | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 1                 | 1                | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 8                 | 8                | Alanine Aminotransferase (U/L) | 7                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 29                | 29               | Alanine Aminotransferase (U/L) | 8                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 36                | 36               | Alanine Aminotransferase (U/L)   | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | -1                | -15              | Alkaline Phosphatase (U/L)       | 60                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 44                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 47                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 29                | 29               | Alkaline Phosphatase (U/L)       | 47                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 36                | 36               | Alkaline Phosphatase (U/L)       | 46                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | -1                | -15              | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 29                | 29               | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 36                | 36               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology                   | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--|-------------------------------------|-------------------------------------|
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | -1                | -15              | Creatinine (mg/dL)           | 0.97              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 1                 | 1                | Creatinine (mg/dL)           | 0.93              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 8                 | 8                | Creatinine (mg/dL)           | 1.00              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 29                | 29               | Creatinine (mg/dL)           | 0.81              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 36                | 36               | Creatinine (mg/dL)           | 0.91              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | -1                | -15              | Hemoglobin (g/dL)            | 15.1              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 1                 | 1                | Hemoglobin (g/dL)            | 13.9              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 8                 | 8                | Hemoglobin (g/dL)            | 13.8 (Mild)       | NOT RELATED                 | study procedures - phlebotomy                          | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 29                | 29               | Hemoglobin (g/dL)            | 13.3 (Mild)       | NOT RELATED                 | related to study procedure                             | NA- NOT APPLICABLE                  | No                                  |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 36                | 36               | Hemoglobin (g/dL)            | 13.6 (Mild)       | NOT RELATED                 | change due to frequent blood draws or normal variation | NA- NOT APPLICABLE                  | No                                  |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | -1                | -15              | PT (seconds)                 | 10.6              | N/A                         | N/A  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | -1                | -15              | PTT (seconds)                   | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | -1                | -15              | Platelets (10 <sup>3</sup> /uL) | 211               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 187               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 186               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 195               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 199               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | -1                | -15              | Serum Lipase (U/L)              | 19.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 1                 | 1                | Serum Lipase (U/L)              | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 8                 | 8                | Serum Lipase (U/L)              | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 29                | 29               | Serum Lipase (U/L)              | 19.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 36                | 36               | Serum Lipase (U/L)              | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | -1                | -15              | Total Bilirubin (mg/dL)         | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 8                 | 8                | Total Bilirubin (mg/dL)        | 1.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 29                | 29               | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 36                | 36               | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | -1                | -15              | WBC (10 <sup>3</sup> /uL)      | 8.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 6.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 5.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 7.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC013  | 250 µg (18-55 years) | FEMALE | 34          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | -1                | -14              | Alanine Aminotransferase (U/L) | 6                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 1                 | 1                | Alanine Aminotransferase (U/L) | 8                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 8                 | 8                | Alanine Aminotransferase (U/L) | 8                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 29                | 28               | Alanine Aminotransferase (U/L)   | 6                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 36                | 35               | Alanine Aminotransferase (U/L)   | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | -1                | -14              | Alkaline Phosphatase (U/L)       | 52                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 51                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 29                | 28               | Alkaline Phosphatase (U/L)       | 45                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 36                | 35               | Alkaline Phosphatase (U/L)       | 51                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | -1                | -14              | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 29                | 28               | Aspartate Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 36                | 35               | Aspartate Aminotransferase (U/L) | 8                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | -1                | -14              | Creatinine (mg/dL)               | 0.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 1                 | 1                | Creatinine (mg/dL)               | 0.86              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 8                 | 8                | Creatinine (mg/dL)               | 0.84              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 29                | 28               | Creatinine (mg/dL)               | 0.83              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 36                | 35               | Creatinine (mg/dL)               | 0.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | -1                | -14              | Hemoglobin (g/dL)                | 13.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 1                 | 1                | Hemoglobin (g/dL)                | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 8                 | 8                | Hemoglobin (g/dL)                | 13.2 (Mild)       | NOT RELATED                 | study procedures - phlebotomy        | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 29                | 28               | Hemoglobin (g/dL)                | 13.0 (Mild)       | NOT RELATED                 | phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 36                | 35               | Hemoglobin (g/dL)                | 12.2 (Moderate)   | NOT RELATED                 | normal variation                     | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | -1                | -14              | PT (seconds)                     | 10.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | -1                | -14              | PTT (seconds)                   | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | -1                | -14              | Platelets (10 <sup>3</sup> /uL) | 270               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 278               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 285               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 29                | 28               | Platelets (10 <sup>3</sup> /uL) | 273               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 238               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | -1                | -14              | Serum Lipase (U/L)              | 13.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 1                 | 1                | Serum Lipase (U/L)              | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 8                 | 8                | Serum Lipase (U/L)              | 19.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 29                | 28               | Serum Lipase (U/L)              | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 36                | 35               | Serum Lipase (U/L)              | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | -1                | -14              | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 8                 | 8                | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 29                | 28               | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 36                | 35               | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | -1                | -14              | WBC (10 <sup>3</sup> /uL)      | 8.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 7.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 8.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 29                | 28               | WBC (10 <sup>3</sup> /uL)      | 7.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC016  | 250 µg (18-55 years) | FEMALE | 38          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 5.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg (56-70 years)  | FEMALE | 57          | -1                | -2               | Alanine Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg (56-70 years)  | FEMALE | 57          | 1                 | 1                | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg (56-70 years)  | FEMALE | 57          | 8                 | 7                | Alanine Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 29                | 29               | Alanine Aminotransferase (U/L)   | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 36                | 35               | Alanine Aminotransferase (U/L)   | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | -1                | -2               | Alkaline Phosphatase (U/L)       | 75                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 76                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 71                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 29                | 29               | Alkaline Phosphatase (U/L)       | 71                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 36                | 35               | Alkaline Phosphatase (U/L)       | 73                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | -1                | -2               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 29                | 29               | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC026  | 25 µg (56-70 years) | FEMALE | 57          | 36                | 35               | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg (56-70 years) | FEMALE | 57          | -1                | -2               | Creatinine (mg/dL)               | 0.95              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg (56-70 years) | FEMALE | 57          | 1                 | 1                | Creatinine (mg/dL)               | 0.97              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg (56-70 years) | FEMALE | 57          | 8                 | 7                | Creatinine (mg/dL)               | 0.86              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg (56-70 years) | FEMALE | 57          | 29                | 29               | Creatinine (mg/dL)               | 0.86              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg (56-70 years) | FEMALE | 57          | 36                | 35               | Creatinine (mg/dL)               | 0.99              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg (56-70 years) | FEMALE | 57          | -1                | -2               | Hemoglobin (g/dL)                | 12.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg (56-70 years) | FEMALE | 57          | 1                 | 1                | Hemoglobin (g/dL)                | 13.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg (56-70 years) | FEMALE | 57          | 8                 | 7                | Hemoglobin (g/dL)                | 12.7 (Mild)       | NOT RELATED                 | related to study blood draws         | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC026  | 25 µg (56-70 years) | FEMALE | 57          | 29                | 29               | Hemoglobin (g/dL)                | 12.1 (Mild)       | NOT RELATED                 | normal variation                     | NA- NOT APPLICABLE                  | No                                  |
| CV01HC026  | 25 µg (56-70 years) | FEMALE | 57          | 36                | 35               | Hemoglobin (g/dL)                | 12.2 (Mild)       | NOT RELATED                 | normal variation                     | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC026  | 25 µg (56-70 years) | FEMALE | 57          | -1                | -2               | PT (seconds)                     | 9.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg (56-70 years) | FEMALE | 57          | -1                | -2               | PTT (seconds)                    | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | -1                | -2               | Platelets (10 <sup>3</sup> /uL) | 332               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 324               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 343               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 308               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 320               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | -1                | -2               | Serum Lipase (U/L)              | 33.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 1                 | 1                | Serum Lipase (U/L)              | 40.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 8                 | 7                | Serum Lipase (U/L)              | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 29                | 29               | Serum Lipase (U/L)              | 35.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 36                | 35               | Serum Lipase (U/L)              | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | -1                | -2               | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 8                 | 7                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 29                | 29               | Total Bilirubin (mg/dL)        | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 36                | 35               | Total Bilirubin (mg/dL)        | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | -1                | -2               | WBC (10 <sup>3</sup> /uL)      | 7.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 6.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 5.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 8.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC026  | 25 µg<br>(56-70 years) | FEMALE | 57          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years) | FEMALE | 69          | -1                | -2               | Alanine Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years) | FEMALE | 69          | 1                 | 1                | Alanine Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years) | FEMALE | 69          | 8                 | 8                | Alanine Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years) | FEMALE | 69          | 29                | 29               | Alanine Aminotransferase (U/L) | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC027  | 25 µg<br>(56-70 years) | FEMALE | 69          | 36                | 36               | Alanine Aminotransferase (U/L)   | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years) | FEMALE | 69          | -1                | -2               | Alkaline Phosphatase (U/L)       | 58                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years) | FEMALE | 69          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 63                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years) | FEMALE | 69          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years) | FEMALE | 69          | 29                | 29               | Alkaline Phosphatase (U/L)       | 62                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years) | FEMALE | 69          | 36                | 36               | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years) | FEMALE | 69          | -1                | -2               | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years) | FEMALE | 69          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years) | FEMALE | 69          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years) | FEMALE | 69          | 29                | 29               | Aspartate Aminotransferase (U/L) | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years) | FEMALE | 69          | 36                | 36               | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | -1                | -2               | Creatinine (mg/dL)              | 0.94              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 1                 | 1                | Creatinine (mg/dL)              | 0.91              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 8                 | 8                | Creatinine (mg/dL)              | 0.88              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 29                | 29               | Creatinine (mg/dL)              | 0.95              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 36                | 36               | Creatinine (mg/dL)              | 0.94              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | -1                | -2               | Hemoglobin (g/dL)               | 14.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 1                 | 1                | Hemoglobin (g/dL)               | 14.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 8                 | 8                | Hemoglobin (g/dL)               | 13.6 (Mild)       | NOT RELATED                 | study procedure (phlebotomy)         | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 29                | 29               | Hemoglobin (g/dL)               | 15.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 36                | 36               | Hemoglobin (g/dL)               | 14.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | -1                | -2               | PT (seconds)                    | 10.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | -1                | -2               | PTT (seconds)                   | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | -1                | -2               | Platelets (10 <sup>3</sup> /uL) | 173               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 180               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 159               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 180               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 188               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | -1                | -2               | Serum Lipase (U/L)              | 60.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 1                 | 1                | Serum Lipase (U/L)              | 67.0 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 8                 | 8                | Serum Lipase (U/L)              | 54.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 29                | 29               | Serum Lipase (U/L)              | 62.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 36                | 36               | Serum Lipase (U/L)              | 43.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | -1                | -2               | Total Bilirubin (mg/dL)         | 1.1               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 1                 | 1                | Total Bilirubin (mg/dL)         | 1.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg (56-70 years) | FEMALE | 69          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group       | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC027  | 25 µg<br>(56-70 years)  | FEMALE | 69          | 36                | 36               | Total Bilirubin (mg/dL)        | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years)  | FEMALE | 69          | -1                | -2               | WBC (10 <sup>3</sup> /uL)      | 5.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years)  | FEMALE | 69          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years)  | FEMALE | 69          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 4.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years)  | FEMALE | 69          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 4.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC027  | 25 µg<br>(56-70 years)  | FEMALE | 69          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 4.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg<br>(56-70 years) | MALE   | 65          | -1                | -6               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg<br>(56-70 years) | MALE   | 65          | 1                 | 1                | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg<br>(56-70 years) | MALE   | 65          | 8                 | 8                | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg<br>(56-70 years) | MALE   | 65          | 29                | 29               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg<br>(56-70 years) | MALE   | 65          | 36                | 36               | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | -1                | -6               | Alkaline Phosphatase (U/L)       | 87                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 82                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 83                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 29                | 29               | Alkaline Phosphatase (U/L)       | 83                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 36                | 36               | Alkaline Phosphatase (U/L)       | 88                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | -1                | -6               | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 29                | 29               | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 36                | 36               | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | -1                | -6               | Creatinine (mg/dL)               | 0.85              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 1                 | 1                | Creatinine (mg/dL)              | 0.93              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 8                 | 8                | Creatinine (mg/dL)              | 0.96              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 29                | 29               | Creatinine (mg/dL)              | 0.91              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 36                | 36               | Creatinine (mg/dL)              | 0.97              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | -1                | -6               | Hemoglobin (g/dL)               | 16.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 1                 | 1                | Hemoglobin (g/dL)               | 15.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 8                 | 8                | Hemoglobin (g/dL)               | 15.0 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 29                | 29               | Hemoglobin (g/dL)               | 15.4 (Mild)       | NOT RELATED                 | normal variation                     | NA- NOT APPLICABLE                  | No                                  |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 36                | 36               | Hemoglobin (g/dL)               | 14.6 (Mild)       | NOT RELATED                 | study procedure or normal variation  | NA- NOT APPLICABLE                  | No                                  |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | -1                | -6               | PT (seconds)                    | 10.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | -1                | -6               | PTT (seconds)                   | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | -1                | -6               | Platelets (10 <sup>3</sup> /uL) | 232               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 226               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 215               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 217               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 234               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | -1                | -6               | Serum Lipase (U/L)              | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 1                 | 1                | Serum Lipase (U/L)              | 19.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 8                 | 8                | Serum Lipase (U/L)              | 23.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 29                | 29               | Serum Lipase (U/L)              | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 36                | 36               | Serum Lipase (U/L)              | 20.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | -1                | -6               | Total Bilirubin (mg/dL)         | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 36                | 36               | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | -1                | -6               | WBC (10 <sup>3</sup> /uL)      | 5.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 5.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 5.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC031  | 100 µg (56-70 years) | MALE | 65          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 5.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg (56-70 years)  | MALE | 71          | -1                | -5               | Alanine Aminotransferase (U/L) | 31                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg (56-70 years)  | MALE | 71          | 1                 | 1                | Alanine Aminotransferase (U/L) | 30                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg (56-70 years)  | MALE | 71          | 8                 | 8                | Alanine Aminotransferase (U/L) | 28                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg (56-70 years)  | MALE | 71          | 29                | 29               | Alanine Aminotransferase (U/L) | 26                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg (56-70 years)  | MALE | 71          | 36                | 37               | Alanine Aminotransferase (U/L) | 28                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | -1                | -5               | Alkaline Phosphatase (U/L)       | 91                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 80                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 84                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 29                | 29               | Alkaline Phosphatase (U/L)       | 86                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 36                | 37               | Alkaline Phosphatase (U/L)       | 88                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | -1                | -5               | Aspartate Aminotransferase (U/L) | 28                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 26                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 29                | 29               | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 36                | 37               | Aspartate Aminotransferase (U/L) | 28                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | -1                | -5               | Creatinine (mg/dL)               | 1.13              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC032  | 25 µg (56-70 years) | MALE | 71          | 1                 | 1                | Creatinine (mg/dL)              | 0.97              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg (56-70 years) | MALE | 71          | 8                 | 8                | Creatinine (mg/dL)              | 1.16              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg (56-70 years) | MALE | 71          | 29                | 29               | Creatinine (mg/dL)              | 1.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg (56-70 years) | MALE | 71          | 36                | 37               | Creatinine (mg/dL)              | 1.12              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg (56-70 years) | MALE | 71          | -1                | -5               | Hemoglobin (g/dL)               | 15.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg (56-70 years) | MALE | 71          | 1                 | 1                | Hemoglobin (g/dL)               | 14.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg (56-70 years) | MALE | 71          | 8                 | 8                | Hemoglobin (g/dL)               | 14.6 (Mild)       | NOT RELATED                 | Normal variation or phlebotomy       | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC032  | 25 µg (56-70 years) | MALE | 71          | 29                | 29               | Hemoglobin (g/dL)               | 14.1 (Mild)       | NOT RELATED                 | normal variation                     | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC032  | 25 µg (56-70 years) | MALE | 71          | 36                | 37               | Hemoglobin (g/dL)               | 14.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg (56-70 years) | MALE | 71          | -1                | -5               | PT (seconds)                    | 10.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg (56-70 years) | MALE | 71          | -1                | -5               | PTT (seconds)                   | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg (56-70 years) | MALE | 71          | -1                | -5               | Platelets (10 <sup>3</sup> /uL) | 279               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg (56-70 years) | MALE | 71          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 278               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 269               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 278               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 296               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | -1                | -5               | Serum Lipase (U/L)              | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 1                 | 1                | Serum Lipase (U/L)              | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 8                 | 8                | Serum Lipase (U/L)              | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 29                | 29               | Serum Lipase (U/L)              | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 36                | 37               | Serum Lipase (U/L)              | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | -1                | -5               | Total Bilirubin (mg/dL)         | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 8                 | 8                | Total Bilirubin (mg/dL)         | 1.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 29                | 29               | Total Bilirubin (mg/dL)         | 1.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 36                | 37               | Total Bilirubin (mg/dL)         | 1.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | -1                | -5               | WBC (10 <sup>3</sup> /uL)      | 7.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 6.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 8.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 7.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC032  | 25 µg<br>(56-70 years) | MALE | 71          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 6.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | -1                | -5               | Alanine Aminotransferase (U/L) | 30                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 1                 | 1                | Alanine Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 8                 | 8                | Alanine Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 29                | 29               | Alanine Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 36                | 37               | Alanine Aminotransferase (U/L) | 28                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | -1                | -5               | Alkaline Phosphatase (U/L)     | 62                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 62                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 58                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 29                | 29               | Alkaline Phosphatase (U/L)       | 54                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 36                | 37               | Alkaline Phosphatase (U/L)       | 56                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | -1                | -5               | Aspartate Aminotransferase (U/L) | 30                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 29                | 29               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 36                | 37               | Aspartate Aminotransferase (U/L) | 29                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | -1                | -5               | Creatinine (mg/dL)               | 1.01              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 1                 | 1                | Creatinine (mg/dL)               | 1.12              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity)  | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|---------------------------------|--------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 8                 | 8                | Creatinine (mg/dL)              | 1.03               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 29                | 29               | Creatinine (mg/dL)              | 1.06               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 36                | 37               | Creatinine (mg/dL)              | 1.04               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | -1                | -5               | Hemoglobin (g/dL)               | 14.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 1                 | 1                | Hemoglobin (g/dL)               | 16.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 8                 | 8                | Hemoglobin (g/dL)               | 14.8<br>(Moderate) | NOT RELATED                 | Large volume phlebotomy at V01       | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 29                | 29               | Hemoglobin (g/dL)               | 14.1<br>(Severe)   | NOT RELATED                 | normal variation                     | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 36                | 37               | Hemoglobin (g/dL)               | 15.5 (Mild)        | NOT RELATED                 | normal variation                     | NA- NOT APPLICABLE                  | No                                  |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | -1                | -5               | PT (seconds)                    | 10.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | -1                | -5               | PTT (seconds)                   | 29.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | -1                | -5               | Platelets (10 <sup>3</sup> /uL) | 280                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 312                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 273                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 271               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 291               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | -1                | -5               | Serum Lipase (U/L)              | 41.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 1                 | 1                | Serum Lipase (U/L)              | 41.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 8                 | 8                | Serum Lipase (U/L)              | 44.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 29                | 29               | Serum Lipase (U/L)              | 39.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 36                | 37               | Serum Lipase (U/L)              | 39.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | -1                | -5               | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | 36                | 37               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years) | MALE | 65          | -1                | -5               | WBC (10 <sup>3</sup> /uL)       | 6.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group       | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC033  | 25 µg<br>(56-70 years)  | MALE   | 65          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years)  | MALE   | 65          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 6.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years)  | MALE   | 65          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 6.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC033  | 25 µg<br>(56-70 years)  | MALE   | 65          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 6.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg<br>(56-70 years) | FEMALE | 58          | -1                | -5               | Alanine Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg<br>(56-70 years) | FEMALE | 58          | 1                 | 1                | Alanine Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg<br>(56-70 years) | FEMALE | 58          | 8                 | 8                | Alanine Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg<br>(56-70 years) | FEMALE | 58          | 29                | 30               | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg<br>(56-70 years) | FEMALE | 58          | 36                | 37               | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg<br>(56-70 years) | FEMALE | 58          | -1                | -5               | Alkaline Phosphatase (U/L)     | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg<br>(56-70 years) | FEMALE | 58          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 57                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 29                | 30               | Alkaline Phosphatase (U/L)       | 52                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 36                | 37               | Alkaline Phosphatase (U/L)       | 54                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | -1                | -5               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 29                | 30               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 36                | 37               | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | -1                | -5               | Creatinine (mg/dL)               | 0.58              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 1                 | 1                | Creatinine (mg/dL)               | 0.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 8                 | 8                | Creatinine (mg/dL)               | 0.56              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 29                | 30               | Creatinine (mg/dL)              | 0.56              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 36                | 37               | Creatinine (mg/dL)              | 0.61              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | -1                | -5               | Hemoglobin (g/dL)               | 13.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 1                 | 1                | Hemoglobin (g/dL)               | 13.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 8                 | 8                | Hemoglobin (g/dL)               | 12.8 (Mild)       | NOT RELATED                 | Large volume phlebotomy at V01       | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 29                | 30               | Hemoglobin (g/dL)               | 12.3 (Mild)       | NOT RELATED                 | frequent blood draws                 | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 36                | 37               | Hemoglobin (g/dL)               | 13.1 (Mild)       | NOT RELATED                 | study procedures or normal variation | NA- NOT APPLICABLE                  | No                                  |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | -1                | -5               | PT (seconds)                    | 10.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | -1                | -5               | PTT (seconds)                   | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | -1                | -5               | Platelets (10 <sup>3</sup> /uL) | 310               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 320               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 316               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 29                | 30               | Platelets (10 <sup>3</sup> /uL) | 287               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 351               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | -1                | -5               | Serum Lipase (U/L)              | 35.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 1                 | 1                | Serum Lipase (U/L)              | 33.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 8                 | 8                | Serum Lipase (U/L)              | 20.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 29                | 30               | Serum Lipase (U/L)              | 23.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 36                | 37               | Serum Lipase (U/L)              | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | -1                | -5               | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 29                | 30               | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 36                | 37               | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | -1                | -5               | WBC (10 <sup>3</sup> /uL)       | 8.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 7.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 5.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 29                | 30               | WBC (10 <sup>3</sup> /uL)      | 5.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC034  | 100 µg (56-70 years) | FEMALE | 58          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 6.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg (56-70 years)  | MALE   | 66          | -1                | -5               | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg (56-70 years)  | MALE   | 66          | 1                 | 1                | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg (56-70 years)  | MALE   | 66          | 8                 | 8                | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg (56-70 years)  | MALE   | 66          | 29                | 29               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg (56-70 years)  | MALE   | 66          | 36                | 37               | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg (56-70 years)  | MALE   | 66          | -1                | -5               | Alkaline Phosphatase (U/L)     | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg (56-70 years)  | MALE   | 66          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC035  | 25 µg (56-70 years) | MALE | 66          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 51                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg (56-70 years) | MALE | 66          | 29                | 29               | Alkaline Phosphatase (U/L)       | 60                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg (56-70 years) | MALE | 66          | 36                | 37               | Alkaline Phosphatase (U/L)       | 60                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg (56-70 years) | MALE | 66          | -1                | -5               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg (56-70 years) | MALE | 66          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg (56-70 years) | MALE | 66          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg (56-70 years) | MALE | 66          | 29                | 29               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg (56-70 years) | MALE | 66          | 36                | 37               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg (56-70 years) | MALE | 66          | -1                | -5               | Creatinine (mg/dL)               | 0.92              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg (56-70 years) | MALE | 66          | 1                 | 1                | Creatinine (mg/dL)               | 0.87              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg (56-70 years) | MALE | 66          | 8                 | 8                | Creatinine (mg/dL)               | 0.93              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity)  | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|---------------------------------|--------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | 29                | 29               | Creatinine (mg/dL)              | 0.93               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | 36                | 37               | Creatinine (mg/dL)              | 0.88               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | -1                | -5               | Hemoglobin (g/dL)               | 14.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | 1                 | 1                | Hemoglobin (g/dL)               | 15.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | 8                 | 8                | Hemoglobin (g/dL)               | 13.6<br>(Moderate) | NOT RELATED                 | Large volume phlebotomy at V01       | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | 29                | 29               | Hemoglobin (g/dL)               | 14.1 (Mild)        | NOT RELATED                 | normal variation                     | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | 36                | 37               | Hemoglobin (g/dL)               | 13.8 (Mild)        | NOT RELATED                 | study procedure or normal variation  | NA- NOT APPLICABLE                  | No                                  |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | -1                | -5               | PT (seconds)                    | 10.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | -1                | -5               | PTT (seconds)                   | 29.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | -1                | -5               | Platelets (10 <sup>3</sup> /uL) | 167                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 167                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 159                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 163               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 206               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | -1                | -5               | Serum Lipase (U/L)              | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | 1                 | 1                | Serum Lipase (U/L)              | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | 8                 | 8                | Serum Lipase (U/L)              | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | 29                | 29               | Serum Lipase (U/L)              | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | 36                | 37               | Serum Lipase (U/L)              | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | -1                | -5               | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | 36                | 37               | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years) | MALE | 66          | -1                | -5               | WBC (10 <sup>3</sup> /uL)       | 5.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group       | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC035  | 25 µg<br>(56-70 years)  | MALE   | 66          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years)  | MALE   | 66          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 5.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years)  | MALE   | 66          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 6.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC035  | 25 µg<br>(56-70 years)  | MALE   | 66          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 6.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg<br>(56-70 years) | FEMALE | 61          | -1                | -6               | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg<br>(56-70 years) | FEMALE | 61          | 1                 | 1                | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg<br>(56-70 years) | FEMALE | 61          | 8                 | 8                | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg<br>(56-70 years) | FEMALE | 61          | 29                | 29               | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg<br>(56-70 years) | FEMALE | 61          | 36                | 36               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg<br>(56-70 years) | FEMALE | 61          | -1                | -6               | Alkaline Phosphatase (U/L)     | 35                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg<br>(56-70 years) | FEMALE | 61          | -1                | -4               | Alkaline Phosphatase (U/L)     | 39                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 39                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 37                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 29                | 29               | Alkaline Phosphatase (U/L)       | 42                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 36                | 36               | Alkaline Phosphatase (U/L)       | 45                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | -1                | -6               | Aspartate Aminotransferase (U/L) | 26                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 29                | 29               | Aspartate Aminotransferase (U/L) | 31                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 36                | 36               | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | -1                | -6               | Creatinine (mg/dL)               | 0.74              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 1                 | 1                | Creatinine (mg/dL)               | 0.67              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 8                 | 8                | Creatinine (mg/dL)              | 0.77              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 29                | 29               | Creatinine (mg/dL)              | 0.75              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 36                | 36               | Creatinine (mg/dL)              | 0.73              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | -1                | -6               | Hemoglobin (g/dL)               | 14.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 1                 | 1                | Hemoglobin (g/dL)               | 14.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 8                 | 8                | Hemoglobin (g/dL)               | 13.5 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 29                | 29               | Hemoglobin (g/dL)               | 14.1 (Mild)       | NOT RELATED                 | normal variation                     | NA- NOT APPLICABLE                  | No                                  |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 36                | 36               | Hemoglobin (g/dL)               | 13.1 (Mild)       | NOT RELATED                 | study procedure or normal variation  | NA- NOT APPLICABLE                  | No                                  |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | -1                | -6               | PT (seconds)                    | 10.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | -1                | -6               | PTT (seconds)                   | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | -1                | -6               | Platelets (10 <sup>3</sup> /uL) | 287               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 284               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 287               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 283               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 278               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | -1                | -6               | Serum Lipase (U/L)              | 36.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 1                 | 1                | Serum Lipase (U/L)              | 38.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 8                 | 8                | Serum Lipase (U/L)              | 34.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 29                | 29               | Serum Lipase (U/L)              | 35.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 36                | 36               | Serum Lipase (U/L)              | 37.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | -1                | -6               | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 36                | 36               | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | -1                | -6               | WBC (10 <sup>3</sup> /uL)      | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 4.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 4.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC037  | 100 µg (56-70 years) | FEMALE | 61          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 3.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE   | 56          | -1                | -5               | Alanine Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE   | 56          | 1                 | 1                | Alanine Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE   | 56          | 8                 | 9                | Alanine Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE   | 56          | 29                | 28               | Alanine Aminotransferase (U/L) | 32                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE   | 56          | 36                | 36               | Alanine Aminotransferase (U/L) | 37                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE   | 56          | -1                | -5               | Alkaline Phosphatase (U/L)     | 74                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 66                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 8                 | 9                | Alkaline Phosphatase (U/L)       | 81                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 29                | 28               | Alkaline Phosphatase (U/L)       | 78                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 36                | 36               | Alkaline Phosphatase (U/L)       | 78                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | -1                | -5               | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 27                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 29                | 28               | Aspartate Aminotransferase (U/L) | 54 (Mild)         | NOT RELATED                 | alcohol consumption                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 36                | 36               | Aspartate Aminotransferase (U/L) | 27                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | -1                | -5               | Creatinine (mg/dL)               | 0.94              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 1                 | 1                | Creatinine (mg/dL)               | 0.99              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 8                 | 9                | Creatinine (mg/dL)              | 1.01              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 29                | 28               | Creatinine (mg/dL)              | 0.96              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 36                | 36               | Creatinine (mg/dL)              | 0.89              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | -1                | -5               | Hemoglobin (g/dL)               | 14.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 1                 | 1                | Hemoglobin (g/dL)               | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 8                 | 9                | Hemoglobin (g/dL)               | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 29                | 28               | Hemoglobin (g/dL)               | 13.8 (Mild)       | NOT RELATED                 | normal variation                     | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 36                | 36               | Hemoglobin (g/dL)               | 13.1 (Mild)       | NOT RELATED                 | study procedure                      | NA- NOT APPLICABLE                  | No                                  |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | -1                | -5               | PT (seconds)                    | 10.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | -1                | -5               | PTT (seconds)                   | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | -1                | -5               | Platelets (10 <sup>3</sup> /uL) | 219               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 221               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 240               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 29                | 28               | Platelets (10 <sup>3</sup> /uL) | 222               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 226               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | -1                | -5               | Serum Lipase (U/L)              | 33.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 1                 | 1                | Serum Lipase (U/L)              | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 8                 | 9                | Serum Lipase (U/L)              | 33.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 29                | 28               | Serum Lipase (U/L)              | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 36                | 36               | Serum Lipase (U/L)              | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | -1                | -5               | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 8                 | 9                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 29                | 28               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 36                | 36               | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | -1                | -5               | WBC (10 <sup>3</sup> /uL)       | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)      | 4.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 29                | 28               | WBC (10 <sup>3</sup> /uL)      | 4.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC038  | 100 µg (56-70 years) | MALE | 56          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 4.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years)  | MALE | 33          | -1                | -4               | Alanine Aminotransferase (U/L) | 29                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years)  | MALE | 33          | 1                 | 1                | Alanine Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years)  | MALE | 33          | 8                 | 8                | Alanine Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years)  | MALE | 33          | 29                | 29               | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years)  | MALE | 33          | 36                | 35               | Alanine Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years)  | MALE | 33          | -1                | -4               | Alkaline Phosphatase (U/L)     | 50                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years)  | MALE | 33          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 40                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 45                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 29                | 29               | Alkaline Phosphatase (U/L)       | 44                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 36                | 35               | Alkaline Phosphatase (U/L)       | 44                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | -1                | -4               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 29                | 29               | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 36                | 35               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | -1                | -4               | Creatinine (mg/dL)               | 1.03              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 1                 | 1                | Creatinine (mg/dL)               | 0.96              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 8                 | 8                | Creatinine (mg/dL)               | 0.94              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 29                | 29               | Creatinine (mg/dL)              | 1.08              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 36                | 35               | Creatinine (mg/dL)              | 1.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | -1                | -4               | Hemoglobin (g/dL)               | 16.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 1                 | 1                | Hemoglobin (g/dL)               | 15.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 8                 | 8                | Hemoglobin (g/dL)               | 15.4 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 29                | 29               | Hemoglobin (g/dL)               | 16.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 36                | 35               | Hemoglobin (g/dL)               | 14.0 (Moderate)   | NOT RELATED                 | related to phlebotomy                | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | -1                | -4               | PT (seconds)                    | 9.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | -1                | -4               | PTT (seconds)                   | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | -1                | -4               | Platelets (10 <sup>3</sup> /uL) | 248               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 233               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 241               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 265               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 233               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | -1                | -4               | Serum Lipase (U/L)              | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 1                 | 1                | Serum Lipase (U/L)              | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 8                 | 8                | Serum Lipase (U/L)              | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 29                | 29               | Serum Lipase (U/L)              | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 36                | 35               | Serum Lipase (U/L)              | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | -1                | -4               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 36                | 35               | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | -1                | -4               | WBC (10 <sup>3</sup> /uL)       | 5.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg (18-55 years) | MALE | 33          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)       | 6.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC048  | 50 µg<br>(18-55 years) | MALE   | 33          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 6.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg<br>(18-55 years) | MALE   | 33          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 5.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC048  | 50 µg<br>(18-55 years) | MALE   | 33          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 6.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg<br>(18-55 years) | FEMALE | 31          | -1                | -3               | Alanine Aminotransferase (U/L) | 7                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg<br>(18-55 years) | FEMALE | 31          | 1                 | 1                | Alanine Aminotransferase (U/L) | 7                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg<br>(18-55 years) | FEMALE | 31          | 8                 | 8                | Alanine Aminotransferase (U/L) | 8                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg<br>(18-55 years) | FEMALE | 31          | 29                | 29               | Alanine Aminotransferase (U/L) | 6                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg<br>(18-55 years) | FEMALE | 31          | 36                | 36               | Alanine Aminotransferase (U/L) | 7                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg<br>(18-55 years) | FEMALE | 31          | -1                | -3               | Alkaline Phosphatase (U/L)     | 41                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg<br>(18-55 years) | FEMALE | 31          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 37                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg<br>(18-55 years) | FEMALE | 31          | 8                 | 8                | Alkaline Phosphatase (U/L)     | 40                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 29                | 29               | Alkaline Phosphatase (U/L)       | 42                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 36                | 36               | Alkaline Phosphatase (U/L)       | 37                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | -1                | -3               | Aspartate Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 29                | 29               | Aspartate Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 36                | 36               | Aspartate Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | -1                | -3               | Creatinine (mg/dL)               | 0.73              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 1                 | 1                | Creatinine (mg/dL)               | 0.73              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 8                 | 8                | Creatinine (mg/dL)               | 0.77              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 29                | 29               | Creatinine (mg/dL)               | 0.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 36                | 36               | Creatinine (mg/dL)              | 0.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | -1                | -3               | Hemoglobin (g/dL)               | 14.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 1                 | 1                | Hemoglobin (g/dL)               | 14.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 8                 | 8                | Hemoglobin (g/dL)               | 13.6 (Mild)       | NOT RELATED                 | study procedure                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 29                | 29               | Hemoglobin (g/dL)               | 13.6 (Mild)       | NOT RELATED                 | normal variation                     | NA- NOT APPLICABLE                  | No                                  |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 36                | 36               | Hemoglobin (g/dL)               | 12.4 (Moderate)   | NOT RELATED                 | related to phlebotomy                | NA- NOT APPLICABLE                  | No                                  |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | -1                | -3               | PT (seconds)                    | 10.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | -1                | -3               | PTT (seconds)                   | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | -1                | -3               | Platelets (10 <sup>3</sup> /uL) | 208               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 206               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 194               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 207               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 224               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | -1                | -3               | Serum Lipase (U/L)           | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 1                 | 1                | Serum Lipase (U/L)           | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 8                 | 8                | Serum Lipase (U/L)           | 20.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 29                | 29               | Serum Lipase (U/L)           | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 36                | 36               | Serum Lipase (U/L)           | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | -1                | -3               | Total Bilirubin (mg/dL)      | 1.1               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 1                 | 1                | Total Bilirubin (mg/dL)      | 1.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 8                 | 8                | Total Bilirubin (mg/dL)      | 1.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 29                | 29               | Total Bilirubin (mg/dL)      | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 36                | 36               | Total Bilirubin (mg/dL)      | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | -1                | -3               | WBC (10 <sup>3</sup> /uL)    | 4.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 4.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)    | 5.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 4.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC050  | 50 µg (18-55 years) | FEMALE | 31          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 4.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | -1                | -4               | Alanine Aminotransferase (U/L) | 8                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 1                 | 1                | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 8                 | 8                | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 29                | 27               | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 36                | 34               | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | -1                | -4               | Alkaline Phosphatase (U/L)     | 46                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 50                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 8                 | 8                | Alkaline Phosphatase (U/L)     | 46                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 29                | 27               | Alkaline Phosphatase (U/L)     | 47                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 36                | 34               | Alkaline Phosphatase (U/L)       | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | -1                | -4               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 29                | 27               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 36                | 34               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | -1                | -4               | Creatinine (mg/dL)               | 0.71              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 1                 | 1                | Creatinine (mg/dL)               | 0.76              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 8                 | 8                | Creatinine (mg/dL)               | 0.83              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 29                | 27               | Creatinine (mg/dL)               | 0.86              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 36                | 34               | Creatinine (mg/dL)               | 0.83              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | -1                | -4               | Hemoglobin (g/dL)               | 13.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 1                 | 1                | Hemoglobin (g/dL)               | 13.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 8                 | 8                | Hemoglobin (g/dL)               | 12.6 (Mild)       | NOT RELATED                 | study procedure                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 29                | 27               | Hemoglobin (g/dL)               | 11.5 (Mild)       | NOT RELATED                 | related to phlebotomy                | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 36                | 34               | Hemoglobin (g/dL)               | 11.9 (Mild)       | NOT RELATED                 | related to blood draws               | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | -1                | -4               | PT (seconds)                    | 10.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | -1                | -4               | PTT (seconds)                   | 31.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | -1                | -4               | Platelets (10 <sup>3</sup> /uL) | 311               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 330               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 316               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 289               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 36                | 34               | Platelets (10 <sup>3</sup> /uL) | 306               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | -1                | -4               | Serum Lipase (U/L)              | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 1                 | 1                | Serum Lipase (U/L)           | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 8                 | 8                | Serum Lipase (U/L)           | 12.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 29                | 27               | Serum Lipase (U/L)           | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 36                | 34               | Serum Lipase (U/L)           | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | -1                | -4               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 8                 | 8                | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 29                | 27               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 36                | 34               | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | -1                | -4               | WBC (10 <sup>3</sup> /uL)    | 7.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 5.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)    | 6.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC051  | 50 µg (18-55 years) | FEMALE | 26          | 29                | 27               | WBC (10 <sup>3</sup> /uL)    | 6.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC051  | 50 µg<br>(18-55 years) | FEMALE | 26          | 36                | 34               | WBC (10 <sup>3</sup> /uL)      | 6.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg<br>(18-55 years) | MALE   | 38          | -1                | -3               | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg<br>(18-55 years) | MALE   | 38          | 1                 | 1                | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg<br>(18-55 years) | MALE   | 38          | 8                 | 8                | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg<br>(18-55 years) | MALE   | 38          | 29                | 27               | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg<br>(18-55 years) | MALE   | 38          | 36                | 34               | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg<br>(18-55 years) | MALE   | 38          | -1                | -3               | Alkaline Phosphatase (U/L)     | 42                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg<br>(18-55 years) | MALE   | 38          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 37                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg<br>(18-55 years) | MALE   | 38          | 8                 | 8                | Alkaline Phosphatase (U/L)     | 39                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg<br>(18-55 years) | MALE   | 38          | 29                | 27               | Alkaline Phosphatase (U/L)     | 38                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg<br>(18-55 years) | MALE   | 38          | 36                | 34               | Alkaline Phosphatase (U/L)     | 38                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | -1                | -3               | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 29                | 27               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 36                | 34               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | -1                | -3               | Creatinine (mg/dL)               | 0.85              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 1                 | 1                | Creatinine (mg/dL)               | 0.75              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 8                 | 8                | Creatinine (mg/dL)               | 0.78              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 29                | 27               | Creatinine (mg/dL)               | 0.75              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 36                | 34               | Creatinine (mg/dL)               | 0.75              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | -1                | -3               | Hemoglobin (g/dL)                | 14.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 1                 | 1                | Hemoglobin (g/dL)               | 14.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 8                 | 8                | Hemoglobin (g/dL)               | 13.4 (Mild)       | NOT RELATED                 | study procedure                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 29                | 27               | Hemoglobin (g/dL)               | 13.4 (Mild)       | NOT RELATED                 | related to phlebotomy                | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 36                | 34               | Hemoglobin (g/dL)               | 13.4 (Mild)       | NOT RELATED                 | related to phlebotomy                | NC- DOSE NOT CHANGED                | No                                  |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | -1                | -3               | PT (seconds)                    | 10.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | -1                | -3               | PTT (seconds)                   | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | -1                | -3               | Platelets (10 <sup>3</sup> /uL) | 258               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 243               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 256               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 236               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 36                | 34               | Platelets (10 <sup>3</sup> /uL) | 249               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | -1                | -3               | Serum Lipase (U/L)              | 37.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 1                 | 1                | Serum Lipase (U/L)              | 31.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 8                 | 8                | Serum Lipase (U/L)           | 51.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 29                | 27               | Serum Lipase (U/L)           | 49.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 36                | 34               | Serum Lipase (U/L)           | 36.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | -1                | -3               | Total Bilirubin (mg/dL)      | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 8                 | 8                | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 29                | 27               | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 36                | 34               | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | -1                | -3               | WBC (10 <sup>3</sup> /uL)    | 6.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 6.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)    | 6.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 29                | 27               | WBC (10 <sup>3</sup> /uL)    | 7.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01HC054  | 50 µg (18-55 years) | MALE | 38          | 36                | 34               | WBC (10 <sup>3</sup> /uL)    | 6.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | -1                | -11              | Alanine Aminotransferase (U/L)   | 34                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 53 (Mild)         | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | 8                 | 8                | Alanine Aminotransferase (U/L)   | 43                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | 29                | 30               | Alanine Aminotransferase (U/L)   | 44                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | 36                | 38               | Alanine Aminotransferase (U/L)   | 46                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | -1                | -11              | Alkaline Phosphatase (U/L)       | 84                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 76                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 71                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | 29                | 30               | Alkaline Phosphatase (U/L)       | 69                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | 36                | 38               | Alkaline Phosphatase (U/L)       | 76                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | -1                | -11              | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | 29                | 30               | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | 36                | 38               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | -1                | -11              | Creatinine (mg/dL)               | 1.03              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | 1                 | 1                | Creatinine (mg/dL)               | 1.07              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | 8                 | 8                | Creatinine (mg/dL)               | 0.96              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | 29                | 30               | Creatinine (mg/dL)               | 0.99              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | 36                | 38               | Creatinine (mg/dL)               | 0.99              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | -1                | -11              | Hemoglobin (g/dL)                | 16.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg (18-55 years) | MALE | 46          | 1                 | 1                | Hemoglobin (g/dL)                | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP001  | 25 µg<br>(18-55 years) | MALE | 46          | 8                 | 8                | Hemoglobin (g/dL)               | 16.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE | 46          | 29                | 30               | Hemoglobin (g/dL)               | 15.8 (Mild)       | NOT RELATED                 | Study procedure                      | NA- NOT APPLICABLE                  | No                                  |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE | 46          | 36                | 38               | Hemoglobin (g/dL)               | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE | 46          | -1                | -11              | PT (seconds)                    | 10.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE | 46          | -1                | -11              | PTT (seconds)                   | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE | 46          | -1                | -11              | Platelets (10 <sup>3</sup> /uL) | 264               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE | 46          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 186               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE | 46          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 225               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE | 46          | 29                | 30               | Platelets (10 <sup>3</sup> /uL) | 183               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE | 46          | 36                | 38               | Platelets (10 <sup>3</sup> /uL) | 193               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE | 46          | -1                | -11              | Serum Lipase (U/L)              | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE | 46          | 1                 | 1                | Serum Lipase (U/L)              | 20.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE | 46          | 8                 | 8                | Serum Lipase (U/L)              | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP001  | 25 µg<br>(18-55 years) | MALE   | 46          | 29                | 30               | Serum Lipase (U/L)             | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE   | 46          | 36                | 38               | Serum Lipase (U/L)             | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE   | 46          | -1                | -11              | Total Bilirubin (mg/dL)        | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE   | 46          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE   | 46          | 8                 | 8                | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE   | 46          | 29                | 30               | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE   | 46          | 36                | 38               | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE   | 46          | -1                | -11              | WBC (10 <sup>3</sup> /uL)      | 7.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE   | 46          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 6.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE   | 46          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 6.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE   | 46          | 29                | 30               | WBC (10 <sup>3</sup> /uL)      | 5.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP001  | 25 µg<br>(18-55 years) | MALE   | 46          | 36                | 38               | WBC (10 <sup>3</sup> /uL)      | 5.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | -1                | -10              | Alanine Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 8                 | 8                | Alanine Aminotransferase (U/L)   | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 29                | 30               | Alanine Aminotransferase (U/L)   | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 36                | 38               | Alanine Aminotransferase (U/L)   | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | -1                | -10              | Alkaline Phosphatase (U/L)       | 50                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 64                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 46                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 29                | 30               | Alkaline Phosphatase (U/L)       | 43                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 36                | 38               | Alkaline Phosphatase (U/L)       | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | -1                | -10              | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 28                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 29                | 30               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 36                | 38               | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | -1                | -10              | Creatinine (mg/dL)               | 0.82              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 1                 | 1                | Creatinine (mg/dL)               | 0.88              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 8                 | 8                | Creatinine (mg/dL)               | 0.85              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 29                | 30               | Creatinine (mg/dL)               | 0.93              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 36                | 38               | Creatinine (mg/dL)               | 0.92              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | -1                | -10              | Hemoglobin (g/dL)                | 13.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 1                 | 1                | Hemoglobin (g/dL)                | 13.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 8                 | 8                | Hemoglobin (g/dL)                | 12.9 (Mild)       | NOT RELATED                 | study procedure                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP005  | 25 µg (18-55 years) | FEMALE | 25          | 29                | 30               | Hemoglobin (g/dL)                | 13.4 (Mild)       | NOT RELATED                 | Study procedure                      | NA- NOT APPLICABLE                  | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | 36                | 38               | Hemoglobin (g/dL)               | 12.9 (Mild)       | NOT RELATED                 | Study procedure                      | NA- NOT APPLICABLE                  | No                                  |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | -1                | -10              | PT (seconds)                    | 11.5 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | -1                | -10              | PTT (seconds)                   | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | -1                | -10              | Platelets (10 <sup>3</sup> /uL) | 269               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 270               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 282               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | 29                | 30               | Platelets (10 <sup>3</sup> /uL) | 290               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | 36                | 38               | Platelets (10 <sup>3</sup> /uL) | 287               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | -1                | -10              | Serum Lipase (U/L)              | 60.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | 1                 | 1                | Serum Lipase (U/L)              | 54.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | 8                 | 8                | Serum Lipase (U/L)              | 46.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | 29                | 30               | Serum Lipase (U/L)              | 50.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | 36                | 38               | Serum Lipase (U/L)              | 48.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | -1                | -10              | Total Bilirubin (mg/dL)        | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | 8                 | 8                | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | 29                | 30               | Total Bilirubin (mg/dL)        | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | 36                | 38               | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | -1                | -10              | WBC (10 <sup>3</sup> /uL)      | 4.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 4.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | 29                | 30               | WBC (10 <sup>3</sup> /uL)      | 3.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP005  | 25 µg<br>(18-55 years) | FEMALE | 25          | 36                | 38               | WBC (10 <sup>3</sup> /uL)      | 4.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | -1                | -10              | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | 1                 | 1                | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | 8                 | 8                | Alanine Aminotransferase (U/L)   | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | 29                | 30               | Alanine Aminotransferase (U/L)   | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | 36                | 38               | Alanine Aminotransferase (U/L)   | 7                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | -1                | -10              | Alkaline Phosphatase (U/L)       | 41                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 45                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 34                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | 29                | 30               | Alkaline Phosphatase (U/L)       | 32                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | 36                | 38               | Alkaline Phosphatase (U/L)       | 33                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | -1                | -10              | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | 29                | 30               | Aspartate Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | 36                | 38               | Aspartate Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | -1                | -10              | Creatinine (mg/dL)               | 0.77              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Creatinine (mg/dL)               | 0.73              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | 8                 | 8                | Creatinine (mg/dL)               | 0.74              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | 29                | 30               | Creatinine (mg/dL)               | 0.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | 36                | 38               | Creatinine (mg/dL)               | 0.73              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | -1                | -10              | Hemoglobin (g/dL)                | 12.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Hemoglobin (g/dL)                | 11.7 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | 8                 | 8                | Hemoglobin (g/dL)                | 11.3 (Mild)       | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | 29                | 30               | Hemoglobin (g/dL)                | 10.6 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | 36                | 38               | Hemoglobin (g/dL)                | 11.2 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | -1                | -10              | PT (seconds)                    | 11.5 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | -1                | -10              | PTT (seconds)                   | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | -1                | -10              | Platelets (10 <sup>3</sup> /uL) | 235               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 224               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 231               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | 29                | 30               | Platelets (10 <sup>3</sup> /uL) | 231               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | 36                | 38               | Platelets (10 <sup>3</sup> /uL) | 274               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | -1                | -10              | Serum Lipase (U/L)              | 43.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | 1                 | 1                | Serum Lipase (U/L)              | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | 8                 | 8                | Serum Lipase (U/L)              | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | 29                | 30               | Serum Lipase (U/L)              | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | 36                | 38               | Serum Lipase (U/L)              | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg<br>(18-55 years) | FEMALE | 32          | -1                | -10              | Total Bilirubin (mg/dL)         | 1.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Total Bilirubin (mg/dL)        | 1.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | 8                 | 8                | Total Bilirubin (mg/dL)        | 1.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | 29                | 30               | Total Bilirubin (mg/dL)        | 1.1               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | 36                | 38               | Total Bilirubin (mg/dL)        | 1.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | -1                | -10              | WBC (10 <sup>3</sup> /uL)      | 5.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 6.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 5.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | 29                | 30               | WBC (10 <sup>3</sup> /uL)      | 6.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP006  | 25 µg (18-55 years) | FEMALE | 32          | 36                | 38               | WBC (10 <sup>3</sup> /uL)      | 5.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | -1                | -10              | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 1                 | 1                | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 8                 | 8                | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 29                | 30               | Alanine Aminotransferase (U/L)   | 8                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 36                | 38               | Alanine Aminotransferase (U/L)   | 8                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | -1                | -10              | Alkaline Phosphatase (U/L)       | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 50                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 41                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 29                | 30               | Alkaline Phosphatase (U/L)       | 39                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 36                | 38               | Alkaline Phosphatase (U/L)       | 43                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | -1                | -10              | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 29                | 30               | Aspartate Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 36                | 38               | Aspartate Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | -1                | -10              | Creatinine (mg/dL)               | 0.79              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 1                 | 1                | Creatinine (mg/dL)               | 0.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 8                 | 8                | Creatinine (mg/dL)               | 0.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 29                | 30               | Creatinine (mg/dL)               | 0.78              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 36                | 38               | Creatinine (mg/dL)               | 0.79              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | -1                | -10              | Hemoglobin (g/dL)                | 12.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 1                 | 1                | Hemoglobin (g/dL)                | 11.7 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 8                 | 8                | Hemoglobin (g/dL)                | 11.6 (Mild)       | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 29                | 30               | Hemoglobin (g/dL)                | 11.3 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | 36                | 38               | Hemoglobin (g/dL)                | 11.3 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | -1                | -10              | PT (seconds)                     | 9.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years) | FEMALE | 44          | -1                | -10              | PTT (seconds)                    | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP007  | 25 µg<br>(18-55 years) | FEMALE | 44          | -1                | -10              | Platelets (10 <sup>3</sup> /uL) | 278               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg<br>(18-55 years) | FEMALE | 44          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 317               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg<br>(18-55 years) | FEMALE | 44          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 319               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg<br>(18-55 years) | FEMALE | 44          | 29                | 30               | Platelets (10 <sup>3</sup> /uL) | 295               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg<br>(18-55 years) | FEMALE | 44          | 36                | 38               | Platelets (10 <sup>3</sup> /uL) | 295               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg<br>(18-55 years) | FEMALE | 44          | -1                | -10              | Serum Lipase (U/L)              | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg<br>(18-55 years) | FEMALE | 44          | 1                 | 1                | Serum Lipase (U/L)              | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg<br>(18-55 years) | FEMALE | 44          | 8                 | 8                | Serum Lipase (U/L)              | 23.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg<br>(18-55 years) | FEMALE | 44          | 29                | 30               | Serum Lipase (U/L)              | 23.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg<br>(18-55 years) | FEMALE | 44          | 36                | 38               | Serum Lipase (U/L)              | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg<br>(18-55 years) | FEMALE | 44          | -1                | -10              | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg<br>(18-55 years) | FEMALE | 44          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg<br>(18-55 years) | FEMALE | 44          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP007  | 25 µg (18-55 years)  | FEMALE | 44          | 29                | 30               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years)  | FEMALE | 44          | 36                | 38               | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years)  | FEMALE | 44          | -1                | -10              | WBC (10 <sup>3</sup> /uL)      | 8.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years)  | FEMALE | 44          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years)  | FEMALE | 44          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 3.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP007  | 25 µg (18-55 years)  | FEMALE | 44          | 29                | 30               | WBC (10 <sup>3</sup> /uL)      | 3.50 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP007  | 25 µg (18-55 years)  | FEMALE | 44          | 36                | 38               | WBC (10 <sup>3</sup> /uL)      | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | -1                | -8               | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 1                 | 1                | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 8                 | 7                | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 29                | 29               | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 36                | 35               | Alanine Aminotransferase (U/L)   | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | -1                | -8               | Alkaline Phosphatase (U/L)       | 66                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 69                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 29                | 29               | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 36                | 35               | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | -1                | -8               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 29                | 29               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 36                | 35               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | -1                | -8               | Creatinine (mg/dL)              | 0.66              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 1                 | 1                | Creatinine (mg/dL)              | 0.66              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 8                 | 7                | Creatinine (mg/dL)              | 0.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 29                | 29               | Creatinine (mg/dL)              | 0.61              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 36                | 35               | Creatinine (mg/dL)              | 0.58              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | -1                | -8               | Hemoglobin (g/dL)               | 14.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 1                 | 1                | Hemoglobin (g/dL)               | 13.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 8                 | 7                | Hemoglobin (g/dL)               | 13.2 (Mild)       | NOT RELATED                 | study procedure                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 29                | 29               | Hemoglobin (g/dL)               | 13.1 (Mild)       | NOT RELATED                 | Study procedure                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 36                | 35               | Hemoglobin (g/dL)               | 13.3 (Mild)       | NOT RELATED                 | Study Procedure                      | NA- NOT APPLICABLE                  | No                                  |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | -1                | -8               | PT (seconds)                    | 10.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | -1                | -8               | PTT (seconds)                   | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | -1                | -8               | Platelets (10 <sup>3</sup> /uL) | 248               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 245               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 251               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 235               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 272               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | -1                | -8               | Serum Lipase (U/L)              | 44.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 1                 | 1                | Serum Lipase (U/L)              | 34.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 8                 | 7                | Serum Lipase (U/L)              | 33.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 29                | 29               | Serum Lipase (U/L)              | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 36                | 35               | Serum Lipase (U/L)              | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | -1                | -8               | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 8                 | 7                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 36                | 35               | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | -1                | -8               | WBC (10 <sup>3</sup> /uL)      | 4.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 4.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 5.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 3.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP008  | 100 µg (18-55 years) | FEMALE | 33          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 4.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | -1                | -8               | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 1                 | 1                | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 8                 | 7                | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 29                | 29               | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 36                | 37               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | -1                | -8               | Alkaline Phosphatase (U/L)       | 50                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 43                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 36                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 29                | 29               | Alkaline Phosphatase (U/L)       | 32                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 36                | 37               | Alkaline Phosphatase (U/L)       | 41                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | -1                | -8               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 29                | 29               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 36                | 37               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | -1                | -8               | Creatinine (mg/dL)               | 0.77              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 1                 | 1                | Creatinine (mg/dL)              | 0.76              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 8                 | 7                | Creatinine (mg/dL)              | 0.69              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 29                | 29               | Creatinine (mg/dL)              | 0.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 36                | 37               | Creatinine (mg/dL)              | 0.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | -1                | -8               | Hemoglobin (g/dL)               | 11.7 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 1                 | 1                | Hemoglobin (g/dL)               | 11.1 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 8                 | 7                | Hemoglobin (g/dL)               | 10.5 (Mild)       | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 29                | 29               | Hemoglobin (g/dL)               | 10.3 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 36                | 37               | Hemoglobin (g/dL)               | 10.6 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | -1                | -8               | PT (seconds)                    | 9.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | -1                | -8               | PTT (seconds)                   | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | -1                | -8               | Platelets (10 <sup>3</sup> /uL) | 307               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 254               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 251               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 243               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 297               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | -1                | -8               | Serum Lipase (U/L)              | 36.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 1                 | 1                | Serum Lipase (U/L)              | 40.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 8                 | 7                | Serum Lipase (U/L)              | 47.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 29                | 29               | Serum Lipase (U/L)              | 51.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 36                | 37               | Serum Lipase (U/L)              | 46.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | -1                | -8               | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 8                 | 7                | Total Bilirubin (mg/dL)         | 0.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 36                | 37               | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | -1                | -8               | WBC (10 <sup>3</sup> /uL)      | 4.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 3.40 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 3.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 3.30 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP009  | 100 µg (18-55 years) | FEMALE | 25          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 3.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years)  | MALE   | 44          | -1                | -15              | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years)  | MALE   | 44          | 1                 | 1                | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years)  | MALE   | 44          | 8                 | 9                | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years)  | MALE   | 44          | 29                | 29               | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years)  | MALE   | 44          | 36                | 37               | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years)  | MALE   | 44          | -1                | -15              | Alkaline Phosphatase (U/L)     | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 63                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 8                 | 9                | Alkaline Phosphatase (U/L)       | 57                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 29                | 29               | Alkaline Phosphatase (U/L)       | 65                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 36                | 37               | Alkaline Phosphatase (U/L)       | 77                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | -1                | -15              | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 29                | 29               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 36                | 37               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | -1                | -15              | Creatinine (mg/dL)               | 1.04              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 1                 | 1                | Creatinine (mg/dL)               | 1.06              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 8                 | 9                | Creatinine (mg/dL)              | 1.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 29                | 29               | Creatinine (mg/dL)              | 1.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 36                | 37               | Creatinine (mg/dL)              | 1.13              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | -1                | -15              | Hemoglobin (g/dL)               | 14.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 1                 | 1                | Hemoglobin (g/dL)               | 14.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 8                 | 9                | Hemoglobin (g/dL)               | 12.9 (Mild)       | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 29                | 29               | Hemoglobin (g/dL)               | 14.1 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 36                | 37               | Hemoglobin (g/dL)               | 14.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | -1                | -15              | PT (seconds)                    | 10.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | -1                | -15              | PTT (seconds)                   | 31.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | -1                | -15              | Platelets (10 <sup>3</sup> /uL) | 245               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 240               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 217               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP010  | 25 µg<br>(18-55 years) | MALE | 44          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 272               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg<br>(18-55 years) | MALE | 44          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 272               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg<br>(18-55 years) | MALE | 44          | -1                | -15              | Serum Lipase (U/L)              | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg<br>(18-55 years) | MALE | 44          | 1                 | 1                | Serum Lipase (U/L)              | 19.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg<br>(18-55 years) | MALE | 44          | 8                 | 9                | Serum Lipase (U/L)              | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg<br>(18-55 years) | MALE | 44          | 29                | 29               | Serum Lipase (U/L)              | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg<br>(18-55 years) | MALE | 44          | 36                | 37               | Serum Lipase (U/L)              | 19.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg<br>(18-55 years) | MALE | 44          | -1                | -15              | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg<br>(18-55 years) | MALE | 44          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg<br>(18-55 years) | MALE | 44          | 8                 | 9                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg<br>(18-55 years) | MALE | 44          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg<br>(18-55 years) | MALE | 44          | 36                | 37               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg<br>(18-55 years) | MALE | 44          | -1                | -15              | WBC (10 <sup>3</sup> /uL)       | 4.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 3.50 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)      | 3.20 (Mild)       | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 4.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP010  | 25 µg (18-55 years) | MALE | 44          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 4.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | -1                | -15              | Alanine Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 1                 | 1                | Alanine Aminotransferase (U/L) | 38                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 8                 | 9                | Alanine Aminotransferase (U/L) | 66 (Mild)         | NOT RELATED                 | increased alcohol night before       | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 29                | 29               | Alanine Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 36                | 37               | Alanine Aminotransferase (U/L) | 42                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | -1                | -15              | Alkaline Phosphatase (U/L)     | 84                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 84                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 8                 | 9                | Alkaline Phosphatase (U/L)       | 66                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 29                | 29               | Alkaline Phosphatase (U/L)       | 75                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 36                | 37               | Alkaline Phosphatase (U/L)       | 75                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | -1                | -15              | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 31                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 29                | 29               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 36                | 37               | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | -1                | -15              | Creatinine (mg/dL)               | 1.13              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 1                 | 1                | Creatinine (mg/dL)               | 1.22              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 8                 | 9                | Creatinine (mg/dL)               | 0.99              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 29                | 29               | Creatinine (mg/dL)              | 1.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 36                | 37               | Creatinine (mg/dL)              | 1.02              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | -1                | -15              | Hemoglobin (g/dL)               | 15.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 1                 | 1                | Hemoglobin (g/dL)               | 15.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 8                 | 9                | Hemoglobin (g/dL)               | 15.4 (Mild)       | NOT RELATED                 | study procedure                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 29                | 29               | Hemoglobin (g/dL)               | 15.3 (Mild)       | NOT RELATED                 | Study procedure                      | NA- NOT APPLICABLE                  | No                                  |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 36                | 37               | Hemoglobin (g/dL)               | 15.5 (Mild)       | NOT RELATED                 | phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | -1                | -15              | PT (seconds)                    | 10.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | -1                | -15              | PTT (seconds)                   | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | -1                | -15              | Platelets (10 <sup>3</sup> /uL) | 221               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 219               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 219               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 232               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 227               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | -1                | -15              | Serum Lipase (U/L)              | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 1                 | 1                | Serum Lipase (U/L)              | 12.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 8                 | 9                | Serum Lipase (U/L)              | 8.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 29                | 29               | Serum Lipase (U/L)              | 11.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 36                | 37               | Serum Lipase (U/L)              | 10.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | -1                | -15              | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 8                 | 9                | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 36                | 37               | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | -1                | -15              | WBC (10 <sup>3</sup> /uL)       | 8.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg (18-55 years) | MALE | 37          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)       | 8.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group       | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP011  | 25 µg<br>(18-55 years)  | MALE   | 37          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)      | 8.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg<br>(18-55 years)  | MALE   | 37          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 8.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP011  | 25 µg<br>(18-55 years)  | MALE   | 37          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 7.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg<br>(18-55 years) | FEMALE | 53          | -1                | -7               | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg<br>(18-55 years) | FEMALE | 53          | 1                 | 1                | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg<br>(18-55 years) | FEMALE | 53          | 8                 | 7                | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg<br>(18-55 years) | FEMALE | 53          | 29                | 29               | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg<br>(18-55 years) | FEMALE | 53          | 36                | 37               | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg<br>(18-55 years) | FEMALE | 53          | -1                | -7               | Alkaline Phosphatase (U/L)     | 60                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg<br>(18-55 years) | FEMALE | 53          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 63                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg<br>(18-55 years) | FEMALE | 53          | 8                 | 7                | Alkaline Phosphatase (U/L)     | 52                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 29                | 29               | Alkaline Phosphatase (U/L)       | 45                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 36                | 37               | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | -1                | -7               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 29                | 29               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 36                | 37               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | -1                | -7               | Creatinine (mg/dL)               | 0.78              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 1                 | 1                | Creatinine (mg/dL)               | 0.83              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 8                 | 7                | Creatinine (mg/dL)               | 0.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 29                | 29               | Creatinine (mg/dL)               | 0.68              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 36                | 37               | Creatinine (mg/dL)              | 0.78              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | -1                | -7               | Hemoglobin (g/dL)               | 12.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 1                 | 1                | Hemoglobin (g/dL)               | 12.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 8                 | 7                | Hemoglobin (g/dL)               | 12.0 (Mild)       | NOT RELATED                 | Study procedure                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 29                | 29               | Hemoglobin (g/dL)               | 11.5 (Mild)       | NOT RELATED                 | Study procedure                      | NA- NOT APPLICABLE                  | No                                  |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 36                | 37               | Hemoglobin (g/dL)               | 11.7 (Mild)       | NOT RELATED                 | Study procedure                      | NA- NOT APPLICABLE                  | No                                  |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 57                | 58               | Hemoglobin (g/dL)               | 11.6 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | -1                | -7               | PT (seconds)                    | 10.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | -1                | -7               | PTT (seconds)                   | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | -1                | -7               | Platelets (10 <sup>3</sup> /uL) | 302               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 290               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 247               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 234               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 260               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | -1                | -7               | Serum Lipase (U/L)              | 38.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 1                 | 1                | Serum Lipase (U/L)              | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 8                 | 7                | Serum Lipase (U/L)              | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 29                | 29               | Serum Lipase (U/L)              | 61.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 36                | 37               | Serum Lipase (U/L)              | 43.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | -1                | -7               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 8                 | 7                | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 36                | 37               | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | -1                | -7               | WBC (10 <sup>3</sup> /uL)       | 5.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)       | 4.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 3.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 4.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP012  | 100 µg (18-55 years) | FEMALE | 53          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 4.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | -1                | -7               | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Alanine Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 8                 | 7                | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 29                | 29               | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 36                | 37               | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | -1                | -7               | Alkaline Phosphatase (U/L)     | 63                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 63                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 8                 | 7                | Alkaline Phosphatase (U/L)     | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 29                | 29               | Alkaline Phosphatase (U/L)       | 47                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 36                | 37               | Alkaline Phosphatase (U/L)       | 63                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | -1                | -7               | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 29                | 29               | Aspartate Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 36                | 37               | Aspartate Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | -1                | -7               | Creatinine (mg/dL)               | 0.66              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Creatinine (mg/dL)               | 0.73              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 8                 | 7                | Creatinine (mg/dL)               | 0.69              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 29                | 29               | Creatinine (mg/dL)               | 0.69              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 36                | 37               | Creatinine (mg/dL)              | 0.74              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | -1                | -7               | Hemoglobin (g/dL)               | 13.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Hemoglobin (g/dL)               | 13.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 8                 | 7                | Hemoglobin (g/dL)               | 13.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 29                | 29               | Hemoglobin (g/dL)               | 12.9 (Mild)       | NOT RELATED                 | Study procedure                      | NA- NOT APPLICABLE                  | No                                  |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 36                | 37               | Hemoglobin (g/dL)               | 13.0 (Mild)       | NOT RELATED                 | Study procedure                      | NA- NOT APPLICABLE                  | No                                  |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | -1                | -7               | PT (seconds)                    | 9.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | -1                | -7               | PTT (seconds)                   | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | -1                | -7               | Platelets (10 <sup>3</sup> /uL) | 240               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 269               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 289               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 246               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 280               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | -1                | -7               | Serum Lipase (U/L)           | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Serum Lipase (U/L)           | 38.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 8                 | 7                | Serum Lipase (U/L)           | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 29                | 29               | Serum Lipase (U/L)           | 34.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 36                | 37               | Serum Lipase (U/L)           | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | -1                | -7               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 8                 | 7                | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 29                | 29               | Total Bilirubin (mg/dL)      | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 36                | 37               | Total Bilirubin (mg/dL)      | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | -1                | -7               | WBC (10 <sup>3</sup> /uL)    | 7.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 7.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)    | 7.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 7.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP014  | 100 µg (18-55 years) | FEMALE | 32          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 6.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years)  | FEMALE | 34          | -1                | -14              | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years)  | FEMALE | 34          | 1                 | 1                | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years)  | FEMALE | 34          | 8                 | 9                | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years)  | FEMALE | 34          | 29                | 29               | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years)  | FEMALE | 34          | 36                | 37               | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years)  | FEMALE | 34          | -1                | -14              | Alkaline Phosphatase (U/L)     | 52                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years)  | FEMALE | 34          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 46                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years)  | FEMALE | 34          | 8                 | 9                | Alkaline Phosphatase (U/L)     | 54                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years)  | FEMALE | 34          | 29                | 29               | Alkaline Phosphatase (U/L)     | 56                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 36                | 37               | Alkaline Phosphatase (U/L)       | 61                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | -1                | -14              | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 29                | 29               | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 36                | 37               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | -1                | -14              | Creatinine (mg/dL)               | 0.82              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 1                 | 1                | Creatinine (mg/dL)               | 0.86              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 8                 | 9                | Creatinine (mg/dL)               | 0.79              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 29                | 29               | Creatinine (mg/dL)               | 0.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 36                | 37               | Creatinine (mg/dL)               | 0.83              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | -1                | -14              | Hemoglobin (g/dL)               | 14.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 1                 | 1                | Hemoglobin (g/dL)               | 13.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 8                 | 9                | Hemoglobin (g/dL)               | 13.1 (Mild)       | NOT RELATED                 | study procedure                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 29                | 29               | Hemoglobin (g/dL)               | 12.5 (Mild)       | NOT RELATED                 | Study Procedure                      | NA- NOT APPLICABLE                  | No                                  |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 36                | 37               | Hemoglobin (g/dL)               | 12.3 (Mild)       | NOT RELATED                 | Study Procedure                      | NA- NOT APPLICABLE                  | No                                  |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | -1                | -14              | PT (seconds)                    | 11.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | -1                | -14              | PTT (seconds)                   | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | -1                | -14              | Platelets (10 <sup>3</sup> /uL) | 280               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 221               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 253               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 231               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 255               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | -1                | -14              | Serum Lipase (U/L)              | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 1                 | 1                | Serum Lipase (U/L)           | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 8                 | 9                | Serum Lipase (U/L)           | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 29                | 29               | Serum Lipase (U/L)           | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 36                | 37               | Serum Lipase (U/L)           | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | -1                | -14              | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 8                 | 9                | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 29                | 29               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 36                | 37               | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | -1                | -14              | WBC (10 <sup>3</sup> /uL)    | 4.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 2.90 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)    | 3.20 (Mild)       | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP015  | 25 µg (18-55 years) | FEMALE | 34          | 29                | 29               | WBC (10 <sup>3</sup> /uL)    | 2.80 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP015  | 25 µg<br>(18-55 years) | FEMALE | 34          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 2.70 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE   | 39          | -1                | -13              | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE   | 39          | 1                 | 1                | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE   | 39          | 15                | 17               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE   | 39          | 29                | 29               | Alanine Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE   | 39          | 36                | 37               | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE   | 39          | -1                | -13              | Alkaline Phosphatase (U/L)     | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE   | 39          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 45                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE   | 39          | 15                | 17               | Alkaline Phosphatase (U/L)     | 44                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE   | 39          | 29                | 29               | Alkaline Phosphatase (U/L)     | 47                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE   | 39          | 36                | 37               | Alkaline Phosphatase (U/L)     | 44                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | -1                | -13              | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 31                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | 15                | 17               | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | 29                | 29               | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | 36                | 37               | Aspartate Aminotransferase (U/L) | 26                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | -1                | -13              | Creatinine (mg/dL)               | 1.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | 1                 | 1                | Creatinine (mg/dL)               | 1.08              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | 15                | 17               | Creatinine (mg/dL)               | 0.97              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | 29                | 29               | Creatinine (mg/dL)               | 0.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | 36                | 37               | Creatinine (mg/dL)               | 0.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | -1                | -13              | Hemoglobin (g/dL)                | 14.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | 1                 | 1                | Hemoglobin (g/dL)               | 14.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | 15                | 17               | Hemoglobin (g/dL)               | 13.8 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | 29                | 29               | Hemoglobin (g/dL)               | 14.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | 36                | 37               | Hemoglobin (g/dL)               | 14.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | -1                | -13              | PT (seconds)                    | 10.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | -1                | -13              | PTT (seconds)                   | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | -1                | -13              | Platelets (10 <sup>3</sup> /uL) | 192               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 200               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | 15                | 17               | Platelets (10 <sup>3</sup> /uL) | 193               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 191               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 179               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | -1                | -13              | Serum Lipase (U/L)              | 46.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg (18-55 years) | MALE | 39          | 1                 | 1                | Serum Lipase (U/L)              | 36.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP018  | 25 µg<br>(18-55 years) | MALE | 39          | 15                | 17               | Serum Lipase (U/L)           | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE | 39          | 29                | 29               | Serum Lipase (U/L)           | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE | 39          | 36                | 37               | Serum Lipase (U/L)           | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE | 39          | -1                | -13              | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE | 39          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE | 39          | 15                | 17               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE | 39          | 29                | 29               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE | 39          | 36                | 37               | Total Bilirubin (mg/dL)      | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE | 39          | -1                | -13              | WBC (10 <sup>3</sup> /uL)    | 5.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE | 39          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE | 39          | 15                | 17               | WBC (10 <sup>3</sup> /uL)    | 3.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE | 39          | 29                | 29               | WBC (10 <sup>3</sup> /uL)    | 3.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP018  | 25 µg<br>(18-55 years) | MALE | 39          | 36                | 37               | WBC (10 <sup>3</sup> /uL)    | 4.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | -1                | -12              | Alanine Aminotransferase (U/L)   | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 8                 | 9                | Alanine Aminotransferase (U/L)   | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 29                | 29               | Alanine Aminotransferase (U/L)   | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 36                | 37               | Alanine Aminotransferase (U/L)   | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | -1                | -12              | Alkaline Phosphatase (U/L)       | 54                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 8                 | 9                | Alkaline Phosphatase (U/L)       | 47                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 29                | 29               | Alkaline Phosphatase (U/L)       | 50                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 36                | 37               | Alkaline Phosphatase (U/L)       | 57                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | -1                | -12              | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 29                | 29               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 36                | 37               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | -1                | -12              | Creatinine (mg/dL)               | 0.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 1                 | 1                | Creatinine (mg/dL)               | 0.89              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 8                 | 9                | Creatinine (mg/dL)               | 0.83              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 29                | 29               | Creatinine (mg/dL)               | 0.84              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 36                | 37               | Creatinine (mg/dL)               | 0.99              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | -1                | -12              | Hemoglobin (g/dL)                | 14.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 1                 | 1                | Hemoglobin (g/dL)                | 14.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 8                 | 9                | Hemoglobin (g/dL)               | 14.1 (Mild)       | NOT RELATED                 | study procedure                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 29                | 29               | Hemoglobin (g/dL)               | 13.8 (Mild)       | NOT RELATED                 | Study procedure                      | NA- NOT APPLICABLE                  | No                                  |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 36                | 37               | Hemoglobin (g/dL)               | 13.8 (Mild)       | NOT RELATED                 | Study procedure                      | NA- NOT APPLICABLE                  | No                                  |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | -1                | -12              | PT (seconds)                    | 10.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | -1                | -12              | PTT (seconds)                   | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | -1                | -12              | Platelets (10 <sup>3</sup> /uL) | 313               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 264               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 227               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 273               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 274               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | -1                | -12              | Serum Lipase (U/L)              | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 1                 | 1                | Serum Lipase (U/L)              | 19.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg (18-55 years) | MALE | 33          | 8                 | 9                | Serum Lipase (U/L)              | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP023  | 25 µg<br>(18-55 years) | MALE | 33          | 29                | 29               | Serum Lipase (U/L)             | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg<br>(18-55 years) | MALE | 33          | 36                | 37               | Serum Lipase (U/L)             | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg<br>(18-55 years) | MALE | 33          | -1                | -12              | Total Bilirubin (mg/dL)        | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg<br>(18-55 years) | MALE | 33          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg<br>(18-55 years) | MALE | 33          | 8                 | 9                | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg<br>(18-55 years) | MALE | 33          | 29                | 29               | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg<br>(18-55 years) | MALE | 33          | 36                | 37               | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg<br>(18-55 years) | MALE | 33          | -1                | -12              | WBC (10 <sup>3</sup> /uL)      | 5.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg<br>(18-55 years) | MALE | 33          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg<br>(18-55 years) | MALE | 33          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)      | 5.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg<br>(18-55 years) | MALE | 33          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 4.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP023  | 25 µg<br>(18-55 years) | MALE | 33          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg<br>(18-55 years) | MALE | 41          | -1                | -12              | Alanine Aminotransferase (U/L) | 48                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | -1                | -7               | Alanine Aminotransferase (U/L) | 44                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 1                 | 1                | Alanine Aminotransferase (U/L) | 41                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 8                 | 9                | Alanine Aminotransferase (U/L) | 43                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 29                | 29               | Alanine Aminotransferase (U/L) | 32                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 36                | 36               | Alanine Aminotransferase (U/L) | 32                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | -1                | -12              | Alkaline Phosphatase (U/L)     | 58                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | -1                | -7               | Alkaline Phosphatase (U/L)     | 71                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 8                 | 9                | Alkaline Phosphatase (U/L)     | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 29                | 29               | Alkaline Phosphatase (U/L)     | 61                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 36                | 36               | Alkaline Phosphatase (U/L)     | 58                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | -1                | -12              | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | -1                | -7               | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 26                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 29                | 29               | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 36                | 36               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | -1                | -12              | Creatinine (mg/dL)               | 1.09              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | -1                | -7               | Creatinine (mg/dL)               | 1.04              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 1                 | 1                | Creatinine (mg/dL)               | 1.03              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 8                 | 9                | Creatinine (mg/dL)               | 0.94              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 29                | 29               | Creatinine (mg/dL)               | 1.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 36                | 36               | Creatinine (mg/dL)              | 1.07              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | -1                | -12              | Hemoglobin (g/dL)               | 16.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 1                 | 1                | Hemoglobin (g/dL)               | 16.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 8                 | 9                | Hemoglobin (g/dL)               | 16.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 29                | 29               | Hemoglobin (g/dL)               | 15.8 (Mild)       | NOT RELATED                 | Study procedure                      | NA- NOT APPLICABLE                  | No                                  |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 36                | 36               | Hemoglobin (g/dL)               | 15.8 (Mild)       | NOT RELATED                 | Study procedure                      | NA- NOT APPLICABLE                  | No                                  |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | -1                | -12              | PT (seconds)                    | 10.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | -1                | -12              | PTT (seconds)                   | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | -1                | -12              | Platelets (10 <sup>3</sup> /uL) | 298               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 285               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 311               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 309               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg (18-55 years) | MALE | 41          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 310               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP024  | 25 µg<br>(18-55 years) | MALE | 41          | -1                | -12              | Serum Lipase (U/L)           | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg<br>(18-55 years) | MALE | 41          | 1                 | 1                | Serum Lipase (U/L)           | 16.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg<br>(18-55 years) | MALE | 41          | 8                 | 9                | Serum Lipase (U/L)           | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg<br>(18-55 years) | MALE | 41          | 29                | 29               | Serum Lipase (U/L)           | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg<br>(18-55 years) | MALE | 41          | 36                | 36               | Serum Lipase (U/L)           | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg<br>(18-55 years) | MALE | 41          | -1                | -12              | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg<br>(18-55 years) | MALE | 41          | -1                | -7               | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg<br>(18-55 years) | MALE | 41          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg<br>(18-55 years) | MALE | 41          | 8                 | 9                | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg<br>(18-55 years) | MALE | 41          | 29                | 29               | Total Bilirubin (mg/dL)      | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg<br>(18-55 years) | MALE | 41          | 36                | 36               | Total Bilirubin (mg/dL)      | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg<br>(18-55 years) | MALE | 41          | -1                | -12              | WBC (10 <sup>3</sup> /uL)    | 6.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg<br>(18-55 years) | MALE | 41          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 5.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP024  | 25 µg<br>(18-55 years) | MALE | 41          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)      | 5.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg<br>(18-55 years) | MALE | 41          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 5.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP024  | 25 µg<br>(18-55 years) | MALE | 41          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 5.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | -1                | -11              | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | 1                 | 1                | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | 8                 | 9                | Alanine Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | 29                | 29               | Alanine Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | 36                | 37               | Alanine Aminotransferase (U/L) | 45                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | -1                | -11              | Alkaline Phosphatase (U/L)     | 62                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 77                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | 8                 | 9                | Alkaline Phosphatase (U/L)     | 62                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | 29                | 29               | Alkaline Phosphatase (U/L)       | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | 36                | 37               | Alkaline Phosphatase (U/L)       | 74                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | -1                | -11              | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 27                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | 29                | 29               | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | 36                | 37               | Aspartate Aminotransferase (U/L) | 45 (Mild)         | NOT RELATED                 | Alcohol intake                       | NA- NOT APPLICABLE                  | No                                  |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | -1                | -11              | Creatinine (mg/dL)               | 0.71              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | 1                 | 1                | Creatinine (mg/dL)               | 0.69              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | 8                 | 9                | Creatinine (mg/dL)               | 0.67              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | 29                | 29               | Creatinine (mg/dL)               | 0.67              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | 36                | 37               | Creatinine (mg/dL)              | 0.65              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | -1                | -11              | Hemoglobin (g/dL)               | 15.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | 1                 | 1                | Hemoglobin (g/dL)               | 15.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | 8                 | 9                | Hemoglobin (g/dL)               | 15.2 (Mild)       | NOT RELATED                 | study procedure                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | 29                | 29               | Hemoglobin (g/dL)               | 15.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | 36                | 37               | Hemoglobin (g/dL)               | 16.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | -1                | -11              | PT (seconds)                    | 10.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | -1                | -11              | PTT (seconds)                   | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | -1                | -11              | Platelets (10 <sup>3</sup> /uL) | 286               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 248               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 251               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 249               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg (18-55 years) | MALE | 53          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 257               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | -1                | -11              | Serum Lipase (U/L)           | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | 1                 | 1                | Serum Lipase (U/L)           | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | 8                 | 9                | Serum Lipase (U/L)           | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | 29                | 29               | Serum Lipase (U/L)           | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | 36                | 37               | Serum Lipase (U/L)           | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | -1                | -11              | Total Bilirubin (mg/dL)      | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | 8                 | 9                | Total Bilirubin (mg/dL)      | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | 29                | 29               | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | 36                | 37               | Total Bilirubin (mg/dL)      | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | -1                | -11              | WBC (10 <sup>3</sup> /uL)    | 6.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE | 53          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)    | 5.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP027  | 25 µg<br>(18-55 years) | MALE   | 53          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 4.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP027  | 25 µg<br>(18-55 years) | MALE   | 53          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 3.50 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | -1                | -11              | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | 1                 | 1                | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | 8                 | 9                | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | 29                | 29               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | 36                | 37               | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | -1                | -11              | Alkaline Phosphatase (U/L)     | 54                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | 8                 | 9                | Alkaline Phosphatase (U/L)     | 43                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | 29                | 29               | Alkaline Phosphatase (U/L)     | 48                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | 36                | 37               | Alkaline Phosphatase (U/L)       | 48                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | -1                | -11              | Aspartate Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | 29                | 29               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | 36                | 37               | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | -1                | -11              | Creatinine (mg/dL)               | 0.52              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | 1                 | 1                | Creatinine (mg/dL)               | 0.58              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | 8                 | 9                | Creatinine (mg/dL)               | 0.57              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | 29                | 29               | Creatinine (mg/dL)               | 0.59              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | 36                | 37               | Creatinine (mg/dL)               | 0.53              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | -1                | -11              | Hemoglobin (g/dL)               | 14.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | 1                 | 1                | Hemoglobin (g/dL)               | 13.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | 8                 | 9                | Hemoglobin (g/dL)               | 13.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | 29                | 29               | Hemoglobin (g/dL)               | 12.7 (Mild)       | NOT RELATED                 | Study procedure                      | NA- NOT APPLICABLE                  | No                                  |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | 36                | 37               | Hemoglobin (g/dL)               | 13.2 (Mild)       | NOT RELATED                 | Study procedure                      | NA- NOT APPLICABLE                  | No                                  |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | -1                | -11              | PT (seconds)                    | 10.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | -1                | -11              | PTT (seconds)                   | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | -1                | -11              | Platelets (10 <sup>3</sup> /uL) | 241               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 249               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 293               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 224               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 257               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg (18-55 years) | FEMALE | 28          | -1                | -11              | Serum Lipase (U/L)              | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | 1                 | 1                | Serum Lipase (U/L)           | 11.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | 8                 | 9                | Serum Lipase (U/L)           | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | 29                | 29               | Serum Lipase (U/L)           | 10.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | 36                | 37               | Serum Lipase (U/L)           | 12.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | -1                | -11              | Total Bilirubin (mg/dL)      | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | 8                 | 9                | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | 29                | 29               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | 36                | 37               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | -1                | -11              | WBC (10 <sup>3</sup> /uL)    | 5.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 5.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)    | 6.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP028  | 25 µg<br>(18-55 years) | FEMALE | 28          | 29                | 29               | WBC (10 <sup>3</sup> /uL)    | 5.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group       | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP028  | 25 µg<br>(18-55 years)  | FEMALE | 28          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 5.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg<br>(18-55 years) | MALE   | 22          | -1                | -26              | Alanine Aminotransferase (U/L) | 35                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg<br>(18-55 years) | MALE   | 22          | 1                 | 1                | Alanine Aminotransferase (U/L) | 53 (Mild)         | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg<br>(18-55 years) | MALE   | 22          | 8                 | 8                | Alanine Aminotransferase (U/L) | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg<br>(18-55 years) | MALE   | 22          | 29                | 28               | Alanine Aminotransferase (U/L) | 28                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg<br>(18-55 years) | MALE   | 22          | 36                | 35               | Alanine Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg<br>(18-55 years) | MALE   | 22          | -1                | -26              | Alkaline Phosphatase (U/L)     | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg<br>(18-55 years) | MALE   | 22          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 73                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg<br>(18-55 years) | MALE   | 22          | 8                 | 8                | Alkaline Phosphatase (U/L)     | 65                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg<br>(18-55 years) | MALE   | 22          | 29                | 28               | Alkaline Phosphatase (U/L)     | 78                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg<br>(18-55 years) | MALE   | 22          | 36                | 35               | Alkaline Phosphatase (U/L)     | 58                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | -1                | -26              | Aspartate Aminotransferase (U/L) | 28                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 38                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 29                | 28               | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 36                | 35               | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | -1                | -26              | Creatinine (mg/dL)               | 0.95              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 1                 | 1                | Creatinine (mg/dL)               | 1.09              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 8                 | 8                | Creatinine (mg/dL)               | 0.97              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 29                | 28               | Creatinine (mg/dL)               | 0.99              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 36                | 35               | Creatinine (mg/dL)               | 0.97              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | -1                | -26              | Hemoglobin (g/dL)                | 16.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 1                 | 1                | Hemoglobin (g/dL)               | 16.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 8                 | 8                | Hemoglobin (g/dL)               | 14.7 (Moderate)   | NOT RELATED                 | Study procedure                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 29                | 28               | Hemoglobin (g/dL)               | 16.1 (Mild)       | NOT RELATED                 | phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 36                | 35               | Hemoglobin (g/dL)               | 16.2 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | -1                | -26              | PT (seconds)                    | 10.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | -1                | -26              | PTT (seconds)                   | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | -1                | -26              | Platelets (10 <sup>3</sup> /uL) | 251               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 223               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 252               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 29                | 28               | Platelets (10 <sup>3</sup> /uL) | 195               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 269               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | -1                | -26              | Serum Lipase (U/L)              | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 1                 | 1                | Serum Lipase (U/L)              | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 8                 | 8                | Serum Lipase (U/L)           | 23.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 29                | 28               | Serum Lipase (U/L)           | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 36                | 35               | Serum Lipase (U/L)           | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | -1                | -26              | Total Bilirubin (mg/dL)      | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 8                 | 8                | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 29                | 28               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 36                | 35               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | -1                | -26              | WBC (10 <sup>3</sup> /uL)    | 4.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 4.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)    | 4.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 29                | 28               | WBC (10 <sup>3</sup> /uL)    | 3.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP030  | 250 µg (18-55 years) | MALE | 22          | 36                | 35               | WBC (10 <sup>3</sup> /uL)    | 3.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | -1                | -11              | Alanine Aminotransferase (U/L)   | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 8                 | 9                | Alanine Aminotransferase (U/L)   | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 29                | 29               | Alanine Aminotransferase (U/L)   | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 36                | 37               | Alanine Aminotransferase (U/L)   | 27                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | -1                | -11              | Alkaline Phosphatase (U/L)       | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 45                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 8                 | 9                | Alkaline Phosphatase (U/L)       | 43                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 29                | 29               | Alkaline Phosphatase (U/L)       | 50                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 36                | 37               | Alkaline Phosphatase (U/L)       | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | -1                | -11              | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 29                | 29               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 36                | 37               | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | -1                | -11              | Creatinine (mg/dL)               | 0.94              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 1                 | 1                | Creatinine (mg/dL)               | 0.98              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 8                 | 9                | Creatinine (mg/dL)               | 0.98              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 29                | 29               | Creatinine (mg/dL)               | 0.94              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 36                | 37               | Creatinine (mg/dL)               | 0.91              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | -1                | -11              | Hemoglobin (g/dL)                | 14.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 1                 | 1                | Hemoglobin (g/dL)                | 13.4 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 8                 | 9                | Hemoglobin (g/dL)               | 13.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 29                | 29               | Hemoglobin (g/dL)               | 13.0 (Mild)       | NOT RELATED                 | phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 36                | 37               | Hemoglobin (g/dL)               | 13.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | -1                | -11              | PT (seconds)                    | 10.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | -1                | -11              | PTT (seconds)                   | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | -1                | -11              | Platelets (10 <sup>3</sup> /uL) | 200               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 172               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 167               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 148               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 163               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | -1                | -11              | Serum Lipase (U/L)              | 19.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 1                 | 1                | Serum Lipase (U/L)              | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg (18-55 years) | MALE | 31          | 8                 | 9                | Serum Lipase (U/L)              | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP031  | 25 µg<br>(18-55 years) | MALE | 31          | 29                | 29               | Serum Lipase (U/L)             | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg<br>(18-55 years) | MALE | 31          | 36                | 37               | Serum Lipase (U/L)             | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg<br>(18-55 years) | MALE | 31          | -1                | -11              | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg<br>(18-55 years) | MALE | 31          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg<br>(18-55 years) | MALE | 31          | 8                 | 9                | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg<br>(18-55 years) | MALE | 31          | 29                | 29               | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg<br>(18-55 years) | MALE | 31          | 36                | 37               | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg<br>(18-55 years) | MALE | 31          | -1                | -11              | WBC (10 <sup>3</sup> /uL)      | 7.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg<br>(18-55 years) | MALE | 31          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg<br>(18-55 years) | MALE | 31          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)      | 5.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg<br>(18-55 years) | MALE | 31          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP031  | 25 µg<br>(18-55 years) | MALE | 31          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 5.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg<br>(18-55 years) | MALE | 27          | -1                | -8               | Alanine Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 8                 | 9                | Alanine Aminotransferase (U/L)   | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 29                | 29               | Alanine Aminotransferase (U/L)   | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 36                | 37               | Alanine Aminotransferase (U/L)   | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | -1                | -8               | Alkaline Phosphatase (U/L)       | 82                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 73                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 8                 | 9                | Alkaline Phosphatase (U/L)       | 70                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 29                | 29               | Alkaline Phosphatase (U/L)       | 78                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 36                | 37               | Alkaline Phosphatase (U/L)       | 78                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | -1                | -8               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 29                | 29               | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 36                | 37               | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | -1                | -8               | Creatinine (mg/dL)               | 1.03              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 1                 | 1                | Creatinine (mg/dL)               | 0.88              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 8                 | 9                | Creatinine (mg/dL)               | 0.73              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 29                | 29               | Creatinine (mg/dL)               | 0.78              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 36                | 37               | Creatinine (mg/dL)               | 0.83              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | -1                | -8               | Hemoglobin (g/dL)                | 15.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 1                 | 1                | Hemoglobin (g/dL)                | 15.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 8                 | 9                | Hemoglobin (g/dL)                | 14.6 (Mild)       | NOT RELATED                 | study procedure                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP032  | 25 µg (18-55 years) | MALE | 27          | 29                | 29               | Hemoglobin (g/dL)                | 14.9 (Mild)       | NOT RELATED                 | Study Procedure                      | NA- NOT APPLICABLE                  | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP032  | 25 µg<br>(18-55 years) | MALE | 27          | 36                | 37               | Hemoglobin (g/dL)               | 15.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg<br>(18-55 years) | MALE | 27          | -1                | -8               | PT (seconds)                    | 10.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg<br>(18-55 years) | MALE | 27          | -1                | -8               | PTT (seconds)                   | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg<br>(18-55 years) | MALE | 27          | -1                | -8               | Platelets (10 <sup>3</sup> /uL) | 327               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg<br>(18-55 years) | MALE | 27          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 312               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg<br>(18-55 years) | MALE | 27          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 324               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg<br>(18-55 years) | MALE | 27          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 302               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg<br>(18-55 years) | MALE | 27          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 335               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg<br>(18-55 years) | MALE | 27          | -1                | -8               | Serum Lipase (U/L)              | 34.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg<br>(18-55 years) | MALE | 27          | 1                 | 1                | Serum Lipase (U/L)              | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg<br>(18-55 years) | MALE | 27          | 8                 | 9                | Serum Lipase (U/L)              | 23.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg<br>(18-55 years) | MALE | 27          | 29                | 29               | Serum Lipase (U/L)              | 31.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg<br>(18-55 years) | MALE | 27          | 36                | 37               | Serum Lipase (U/L)              | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP032  | 25 µg (18-55 years)  | MALE   | 27          | -1                | -8               | Total Bilirubin (mg/dL)        | 1.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years)  | MALE   | 27          | 1                 | 1                | Total Bilirubin (mg/dL)        | 1.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years)  | MALE   | 27          | 8                 | 9                | Total Bilirubin (mg/dL)        | 1.6 (Mild)        | NOT RELATED                 | suspected gilberts                   | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP032  | 25 µg (18-55 years)  | MALE   | 27          | 29                | 29               | Total Bilirubin (mg/dL)        | 2.1 (Moderate)    | NOT RELATED                 | suspected Gilberts                   | NA- NOT APPLICABLE                  | No                                  |
| CV01KP032  | 25 µg (18-55 years)  | MALE   | 27          | 36                | 37               | Total Bilirubin (mg/dL)        | 1.8 (Mild)        | NOT RELATED                 | Other                                | NA- NOT APPLICABLE                  | No                                  |
| CV01KP032  | 25 µg (18-55 years)  | MALE   | 27          | -1                | -8               | WBC (10 <sup>3</sup> /uL)      | 8.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years)  | MALE   | 27          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years)  | MALE   | 27          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)      | 6.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years)  | MALE   | 27          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 6.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP032  | 25 µg (18-55 years)  | MALE   | 27          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 6.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | -1                | -22              | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 1                 | 1                | Alanine Aminotransferase (U/L) | 8                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 8                 | 8                | Alanine Aminotransferase (U/L)   | 8                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 29                | 28               | Alanine Aminotransferase (U/L)   | 8                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 36                | 35               | Alanine Aminotransferase (U/L)   | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | -1                | -22              | Alkaline Phosphatase (U/L)       | 31                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 45                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 39                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 29                | 28               | Alkaline Phosphatase (U/L)       | 39                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 36                | 35               | Alkaline Phosphatase (U/L)       | 35                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | -1                | -22              | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 29                | 28               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 36                | 35               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | -1                | -22              | Creatinine (mg/dL)               | 0.68              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 1                 | 1                | Creatinine (mg/dL)               | 0.64              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 8                 | 8                | Creatinine (mg/dL)               | 0.63              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 29                | 28               | Creatinine (mg/dL)               | 0.58              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 36                | 35               | Creatinine (mg/dL)               | 0.63              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | -1                | -22              | Hemoglobin (g/dL)                | 13.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 1                 | 1                | Hemoglobin (g/dL)                | 12.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 8                 | 8                | Hemoglobin (g/dL)                | 12.6 (Mild)       | NOT RELATED                 | Study procedure                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 29                | 28               | Hemoglobin (g/dL)                | 12.0 (Mild)       | NOT RELATED                 | phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 36                | 35               | Hemoglobin (g/dL)                | 11.6 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 57                | 56               | Hemoglobin (g/dL)               | 11.5 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | -1                | -22              | PT (seconds)                    | 10.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | -1                | -22              | PTT (seconds)                   | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | -1                | -22              | Platelets (10 <sup>3</sup> /uL) | 234               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 209               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 200               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 29                | 28               | Platelets (10 <sup>3</sup> /uL) | 227               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 219               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | -1                | -22              | Serum Lipase (U/L)              | 13.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 1                 | 1                | Serum Lipase (U/L)              | 13.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 8                 | 8                | Serum Lipase (U/L)              | 12.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 29                | 28               | Serum Lipase (U/L)              | 20.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 36                | 35               | Serum Lipase (U/L)              | 13.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | -1                | -22              | Total Bilirubin (mg/dL)        | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 8                 | 8                | Total Bilirubin (mg/dL)        | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 29                | 28               | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 36                | 35               | Total Bilirubin (mg/dL)        | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | -1                | -22              | WBC (10 <sup>3</sup> /uL)      | 6.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 4.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 4.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 29                | 28               | WBC (10 <sup>3</sup> /uL)      | 4.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP033  | 250 µg (18-55 years) | FEMALE | 29          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 5.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE   | 33          | -1                | -26              | Alanine Aminotransferase (U/L) | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE   | 33          | 1                 | 1                | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 8                 | 8                | Alanine Aminotransferase (U/L)   | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 29                | 29               | Alanine Aminotransferase (U/L)   | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 36                | 36               | Alanine Aminotransferase (U/L)   | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | -1                | -26              | Alkaline Phosphatase (U/L)       | 50                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 44                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 29                | 29               | Alkaline Phosphatase (U/L)       | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 36                | 36               | Alkaline Phosphatase (U/L)       | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | -1                | -26              | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 29                | 29               | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 36                | 36               | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | -1                | -26              | Creatinine (mg/dL)               | 0.83              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 1                 | 1                | Creatinine (mg/dL)               | 0.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 8                 | 8                | Creatinine (mg/dL)               | 0.84              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 29                | 29               | Creatinine (mg/dL)               | 0.87              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 36                | 36               | Creatinine (mg/dL)               | 0.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | -1                | -26              | Hemoglobin (g/dL)                | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 1                 | 1                | Hemoglobin (g/dL)                | 15.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 8                 | 8                | Hemoglobin (g/dL)                | 14.4 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 29                | 29               | Hemoglobin (g/dL)                | 16.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 36                | 36               | Hemoglobin (g/dL)                | 14.8 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | -1                | -26              | PT (seconds)                    | 10.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | -1                | -26              | PTT (seconds)                   | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | -1                | -26              | Platelets (10 <sup>3</sup> /uL) | 241               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 266               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 265               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 287               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 284               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | -1                | -26              | Serum Lipase (U/L)              | 54.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 1                 | 1                | Serum Lipase (U/L)              | 54.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 8                 | 8                | Serum Lipase (U/L)              | 40.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 29                | 29               | Serum Lipase (U/L)              | 58.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | 36                | 36               | Serum Lipase (U/L)              | 61.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE | 33          | -1                | -26              | Total Bilirubin (mg/dL)         | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP036  | 250 µg (18-55 years) | MALE   | 33          | 1                 | 1                | Total Bilirubin (mg/dL)        | 1.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE   | 33          | 8                 | 8                | Total Bilirubin (mg/dL)        | 1.1               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE   | 33          | 29                | 29               | Total Bilirubin (mg/dL)        | 1.5 (Mild)        | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP036  | 250 µg (18-55 years) | MALE   | 33          | 36                | 36               | Total Bilirubin (mg/dL)        | 1.1               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE   | 33          | -1                | -26              | WBC (10 <sup>3</sup> /uL)      | 4.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE   | 33          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE   | 33          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 4.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE   | 33          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP036  | 250 µg (18-55 years) | MALE   | 33          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 5.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | -1                | -21              | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 1                 | 1                | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 8                 | 8                | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 36                | 35               | Alanine Aminotransferase (U/L)   | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | -1                | -21              | Alkaline Phosphatase (U/L)       | 56                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 36                | 35               | Alkaline Phosphatase (U/L)       | 54                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | -1                | -21              | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 36                | 35               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | -1                | -21              | Creatinine (mg/dL)               | 0.56              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 1                 | 1                | Creatinine (mg/dL)               | 0.58              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 8                 | 8                | Creatinine (mg/dL)              | 0.57              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 36                | 35               | Creatinine (mg/dL)              | 0.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | -1                | -21              | Hemoglobin (g/dL)               | 13.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 1                 | 1                | Hemoglobin (g/dL)               | 12.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 8                 | 8                | Hemoglobin (g/dL)               | 12.4 (Mild)       | NOT RELATED                 | Study procedure                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 36                | 35               | Hemoglobin (g/dL)               | 12.6 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | -1                | -21              | PT (seconds)                    | 9.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | -1                | -21              | PTT (seconds)                   | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | -1                | -21              | Platelets (10 <sup>3</sup> /uL) | 317               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 278               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 281               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 301               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | -1                | -21              | Serum Lipase (U/L)              | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 1                 | 1                | Serum Lipase (U/L)             | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 8                 | 8                | Serum Lipase (U/L)             | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 36                | 35               | Serum Lipase (U/L)             | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | -1                | -21              | Total Bilirubin (mg/dL)        | 0.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 8                 | 8                | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 36                | 35               | Total Bilirubin (mg/dL)        | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | -1                | -21              | WBC (10 <sup>3</sup> /uL)      | 7.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 7.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 5.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP037  | 250 µg (18-55 years) | FEMALE | 19          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 6.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE   | 29          | -1                | -20              | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 8                 | 8                | Alanine Aminotransferase (U/L)   | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 29                | 28               | Alanine Aminotransferase (U/L)   | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 36                | 35               | Alanine Aminotransferase (U/L)   | 30                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | -1                | -20              | Alkaline Phosphatase (U/L)       | 105               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 122               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 105               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 29                | 28               | Alkaline Phosphatase (U/L)       | 106               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 36                | 35               | Alkaline Phosphatase (U/L)       | 93                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | -1                | -20              | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 29                | 28               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 36                | 35               | Aspartate Aminotransferase (U/L) | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | -1                | -20              | Creatinine (mg/dL)               | 0.85              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 1                 | 1                | Creatinine (mg/dL)               | 0.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 8                 | 8                | Creatinine (mg/dL)               | 0.78              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 29                | 28               | Creatinine (mg/dL)               | 0.85              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 36                | 35               | Creatinine (mg/dL)               | 0.82              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | -1                | -20              | Hemoglobin (g/dL)                | 15.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 1                 | 1                | Hemoglobin (g/dL)                | 16.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 8                 | 8                | Hemoglobin (g/dL)                | 15.7 (Mild)       | NOT RELATED                 | Study procedure                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 29                | 28               | Hemoglobin (g/dL)                | 16.2 (Mild)       | NOT RELATED                 | phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 36                | 35               | Hemoglobin (g/dL)               | 15.7 (Mild)       | NOT RELATED                 | phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | -1                | -20              | PT (seconds)                    | 10.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | -1                | -20              | PTT (seconds)                   | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | -1                | -20              | Platelets (10 <sup>3</sup> /uL) | 199               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 207               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 190               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 29                | 28               | Platelets (10 <sup>3</sup> /uL) | 174               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 190               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | -1                | -20              | Serum Lipase (U/L)              | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 1                 | 1                | Serum Lipase (U/L)              | 19.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 8                 | 8                | Serum Lipase (U/L)              | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 29                | 28               | Serum Lipase (U/L)              | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE | 29          | 36                | 35               | Serum Lipase (U/L)              | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP040  | 250 µg (18-55 years) | MALE   | 29          | -1                | -20              | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE   | 29          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE   | 29          | 8                 | 8                | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE   | 29          | 29                | 28               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE   | 29          | 36                | 35               | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE   | 29          | -1                | -20              | WBC (10 <sup>3</sup> /uL)      | 5.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE   | 29          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE   | 29          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 5.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE   | 29          | 29                | 28               | WBC (10 <sup>3</sup> /uL)      | 5.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP040  | 250 µg (18-55 years) | MALE   | 29          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 5.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | -1                | -25              | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 8                 | 8                | Alanine Aminotransferase (U/L)   | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 29                | 29               | Alanine Aminotransferase (U/L)   | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 36                | 37               | Alanine Aminotransferase (U/L)   | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | -1                | -25              | Alkaline Phosphatase (U/L)       | 43                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 40                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 44                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 29                | 29               | Alkaline Phosphatase (U/L)       | 36                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 36                | 37               | Alkaline Phosphatase (U/L)       | 40                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | -1                | -25              | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 29                | 29               | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 36                | 37               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | -1                | -25              | Creatinine (mg/dL)               | 0.78              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Creatinine (mg/dL)               | 0.84              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 8                 | 8                | Creatinine (mg/dL)               | 0.88              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 29                | 29               | Creatinine (mg/dL)               | 0.84              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 36                | 37               | Creatinine (mg/dL)               | 0.86              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | -1                | -25              | Hemoglobin (g/dL)                | 13.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Hemoglobin (g/dL)                | 13.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 8                 | 8                | Hemoglobin (g/dL)                | 14.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 29                | 29               | Hemoglobin (g/dL)                | 13.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 36                | 37               | Hemoglobin (g/dL)                | 14.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | -1                | -25              | PT (seconds)                    | 10.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | -1                | -25              | PTT (seconds)                   | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | -1                | -25              | Platelets (10 <sup>3</sup> /uL) | 242               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 245               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 248               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 216               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 261               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | -1                | -25              | Serum Lipase (U/L)              | 33.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Serum Lipase (U/L)              | 36.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 8                 | 8                | Serum Lipase (U/L)              | 39.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 29                | 29               | Serum Lipase (U/L)              | 36.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 36                | 37               | Serum Lipase (U/L)              | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | -1                | -25              | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 8                 | 8                | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 29                | 29               | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 36                | 37               | Total Bilirubin (mg/dL)        | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | -1                | -25              | WBC (10 <sup>3</sup> /uL)      | 3.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 4.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 3.40 (Mild)       | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP041  | 250 µg (18-55 years) | FEMALE | 32          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 4.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE   | 23          | -1                | -24              | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE   | 23          | 1                 | 1                | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE   | 23          | 8                 | 8                | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 29                | 29               | Alanine Aminotransferase (U/L)   | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 36                | 37               | Alanine Aminotransferase (U/L)   | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | -1                | -24              | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 43                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 29                | 29               | Alkaline Phosphatase (U/L)       | 45                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 36                | 37               | Alkaline Phosphatase (U/L)       | 46                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | -1                | -24              | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 29                | 29               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 36                | 37               | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | -1                | -24              | Creatinine (mg/dL)               | 0.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 1                 | 1                | Creatinine (mg/dL)               | 0.84              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 8                 | 8                | Creatinine (mg/dL)               | 0.83              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 29                | 29               | Creatinine (mg/dL)               | 0.74              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 36                | 37               | Creatinine (mg/dL)               | 0.77              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | -1                | -24              | Hemoglobin (g/dL)                | 14.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 1                 | 1                | Hemoglobin (g/dL)                | 14.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 8                 | 8                | Hemoglobin (g/dL)                | 13.9 (Mild)       | NOT RELATED                 | Study procedure                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 29                | 29               | Hemoglobin (g/dL)                | 13.9 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 36                | 37               | Hemoglobin (g/dL)                | 13.8 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | -1                | -24              | PT (seconds)                     | 10.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | -1                | -24              | PTT (seconds)                    | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | -1                | -24              | Platelets (10 <sup>3</sup> /uL) | 204               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 193               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 210               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 204               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 245               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | -1                | -24              | Serum Lipase (U/L)              | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 1                 | 1                | Serum Lipase (U/L)              | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 8                 | 8                | Serum Lipase (U/L)              | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 29                | 29               | Serum Lipase (U/L)              | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 36                | 37               | Serum Lipase (U/L)              | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | -1                | -24              | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE | 23          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP048  | 250 µg (18-55 years) | MALE   | 23          | 29                | 29               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE   | 23          | 36                | 37               | Total Bilirubin (mg/dL)        | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE   | 23          | -1                | -24              | WBC (10 <sup>3</sup> /uL)      | 5.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE   | 23          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 7.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE   | 23          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 6.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE   | 23          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 6.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP048  | 250 µg (18-55 years) | MALE   | 23          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 6.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | -1                | -24              | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 1                 | 1                | Alanine Aminotransferase (U/L) | 26                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 8                 | 8                | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 29                | 29               | Alanine Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 36                | 37               | Alanine Aminotransferase (U/L)   | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | -1                | -24              | Alkaline Phosphatase (U/L)       | 71                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 54                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 29                | 29               | Alkaline Phosphatase (U/L)       | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 36                | 37               | Alkaline Phosphatase (U/L)       | 60                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | -1                | -24              | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 29                | 29               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 36                | 37               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | -1                | -24              | Creatinine (mg/dL)              | 0.69              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 1                 | 1                | Creatinine (mg/dL)              | 0.69              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 8                 | 8                | Creatinine (mg/dL)              | 0.67              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 29                | 29               | Creatinine (mg/dL)              | 0.66              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 36                | 37               | Creatinine (mg/dL)              | 0.77              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | -1                | -24              | Hemoglobin (g/dL)               | 13.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 1                 | 1                | Hemoglobin (g/dL)               | 12.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 8                 | 8                | Hemoglobin (g/dL)               | 11.4 (Mild)       | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 29                | 29               | Hemoglobin (g/dL)               | 11.7 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 36                | 37               | Hemoglobin (g/dL)               | 11.7 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | -1                | -24              | PT (seconds)                    | 10.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | -1                | -24              | PTT (seconds)                   | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | -1                | -24              | Platelets (10 <sup>3</sup> /uL) | 298               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 243               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 247               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 210               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 255               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | -1                | -24              | Serum Lipase (U/L)              | 9.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 1                 | 1                | Serum Lipase (U/L)              | 11.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 8                 | 8                | Serum Lipase (U/L)              | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 29                | 29               | Serum Lipase (U/L)              | 10.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 36                | 37               | Serum Lipase (U/L)              | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | -1                | -24              | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 36                | 37               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | -1                | -24              | WBC (10 <sup>3</sup> /uL)      | 5.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 4.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 4.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP049  | 250 µg (18-55 years) | FEMALE | 30          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 3.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | -1                | -21              | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 1                 | 1                | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 8                 | 8                | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 29                | 29               | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 36                | 37               | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | -1                | -21              | Alkaline Phosphatase (U/L)       | 63                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 54                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 56                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 29                | 29               | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 36                | 37               | Alkaline Phosphatase (U/L)       | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | -1                | -21              | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 29                | 29               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 36                | 37               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | -1                | -21              | Creatinine (mg/dL)               | 0.68              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 1                 | 1                | Creatinine (mg/dL)              | 0.77              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 8                 | 8                | Creatinine (mg/dL)              | 0.67              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 29                | 29               | Creatinine (mg/dL)              | 0.72              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 36                | 37               | Creatinine (mg/dL)              | 0.67              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | -1                | -21              | Hemoglobin (g/dL)               | 12.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 1                 | 1                | Hemoglobin (g/dL)               | 13.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 8                 | 8                | Hemoglobin (g/dL)               | 12.4 (Mild)       | NOT RELATED                 | Study procedure                      | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 29                | 29               | Hemoglobin (g/dL)               | 12.3 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 36                | 37               | Hemoglobin (g/dL)               | 12.5 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | -1                | -21              | PT (seconds)                    | 10.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | -1                | -21              | PTT (seconds)                   | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | -1                | -21              | Platelets (10 <sup>3</sup> /uL) | 189               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 202               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 193               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 216               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 221               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | -1                | -21              | Serum Lipase (U/L)              | 12.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 1                 | 1                | Serum Lipase (U/L)              | 10.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 8                 | 8                | Serum Lipase (U/L)              | 9.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 29                | 29               | Serum Lipase (U/L)              | 11.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 36                | 37               | Serum Lipase (U/L)              | 10.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | -1                | -21              | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 36                | 37               | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group    | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|----------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | -1                | -21              | WBC (10 <sup>3</sup> /uL)      | 7.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 6.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 6.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 5.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP053  | 250 µg (18-55 years) | FEMALE | 31          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 6.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years)    | MALE   | 74          | -1                | -17              | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years)    | MALE   | 74          | 1                 | 1                | Alanine Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years)    | MALE   | 74          | 8                 | 9                | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years)    | MALE   | 74          | 29                | 29               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years)    | MALE   | 74          | 36                | 37               | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years)    | MALE   | 74          | -1                | -17              | Alkaline Phosphatase (U/L)     | 50                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 64                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 8                 | 9                | Alkaline Phosphatase (U/L)       | 67                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 29                | 29               | Alkaline Phosphatase (U/L)       | 66                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 36                | 37               | Alkaline Phosphatase (U/L)       | 67                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | -1                | -17              | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 29                | 29               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 36                | 37               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | -1                | -17              | Creatinine (mg/dL)               | 1.11              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 1                 | 1                | Creatinine (mg/dL)               | 1.21              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 8                 | 9                | Creatinine (mg/dL)              | 1.02              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 29                | 29               | Creatinine (mg/dL)              | 1.02              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 36                | 37               | Creatinine (mg/dL)              | 0.95              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | -1                | -17              | Hemoglobin (g/dL)               | 15.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 1                 | 1                | Hemoglobin (g/dL)               | 15.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 8                 | 9                | Hemoglobin (g/dL)               | 14.5 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 29                | 29               | Hemoglobin (g/dL)               | 15.1 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 36                | 37               | Hemoglobin (g/dL)               | 14.1 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | -1                | -17              | PT (seconds)                    | 10.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | -1                | -17              | PTT (seconds)                   | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | -1                | -17              | Platelets (10 <sup>3</sup> /uL) | 185               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 200               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 210               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 197               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 195               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | -1                | -17              | Serum Lipase (U/L)              | 43.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 1                 | 1                | Serum Lipase (U/L)              | 51.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 8                 | 9                | Serum Lipase (U/L)              | 45.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 29                | 29               | Serum Lipase (U/L)              | 43.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 36                | 37               | Serum Lipase (U/L)              | 44.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | -1                | -17              | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 8                 | 9                | Total Bilirubin (mg/dL)         | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | 36                | 37               | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE | 74          | -1                | -17              | WBC (10 <sup>3</sup> /uL)       | 5.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP059  | 25 µg (≥71 years) | MALE   | 74          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 6.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE   | 74          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)      | 6.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE   | 74          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 6.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP059  | 25 µg (≥71 years) | MALE   | 74          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 6.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | -1                | -17              | Alanine Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 1                 | 1                | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 8                 | 9                | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 29                | 29               | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 36                | 37               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | -1                | -17              | Alkaline Phosphatase (U/L)     | 57                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 61                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 8                 | 9                | Alkaline Phosphatase (U/L)       | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 29                | 29               | Alkaline Phosphatase (U/L)       | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 36                | 37               | Alkaline Phosphatase (U/L)       | 60                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | -1                | -17              | Aspartate Aminotransferase (U/L) | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 29                | 29               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 36                | 37               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | -1                | -17              | Creatinine (mg/dL)               | 0.76              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 1                 | 1                | Creatinine (mg/dL)               | 0.74              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 8                 | 9                | Creatinine (mg/dL)               | 0.68              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 29                | 29               | Creatinine (mg/dL)              | 0.64              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 36                | 37               | Creatinine (mg/dL)              | 0.62              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | -1                | -17              | Hemoglobin (g/dL)               | 13.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 1                 | 1                | Hemoglobin (g/dL)               | 12.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 8                 | 9                | Hemoglobin (g/dL)               | 12.3 (Mild)       | NOT RELATED                 | phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 29                | 29               | Hemoglobin (g/dL)               | 12.6 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 36                | 37               | Hemoglobin (g/dL)               | 12.7 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | -1                | -17              | PT (seconds)                    | 9.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | -1                | -17              | PTT (seconds)                   | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | -1                | -17              | Platelets (10 <sup>3</sup> /uL) | 260               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 250               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 267               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 267               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 265               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | -1                | -17              | Serum Lipase (U/L)              | 51.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 1                 | 1                | Serum Lipase (U/L)              | 52.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 8                 | 9                | Serum Lipase (U/L)              | 47.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 29                | 29               | Serum Lipase (U/L)              | 51.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 36                | 37               | Serum Lipase (U/L)              | 46.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | -1                | -17              | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 8                 | 9                | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 36                | 37               | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | -1                | -17              | WBC (10 <sup>3</sup> /uL)       | 4.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)       | 3.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)      | 4.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 3.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP060  | 25 µg (≥71 years) | FEMALE | 75          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 4.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE   | 72          | -1                | -17              | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE   | 72          | 1                 | 1                | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE   | 72          | 8                 | 9                | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE   | 72          | 29                | 29               | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE   | 72          | 36                | 37               | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE   | 72          | -1                | -17              | Alkaline Phosphatase (U/L)     | 60                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE   | 72          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 74                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE   | 72          | 8                 | 9                | Alkaline Phosphatase (U/L)     | 70                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Alkaline Phosphatase (U/L)       | 68                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Alkaline Phosphatase (U/L)       | 63                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | Creatinine (mg/dL)               | 0.99              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Creatinine (mg/dL)               | 1.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Creatinine (mg/dL)               | 0.95              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Creatinine (mg/dL)               | 0.93              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Creatinine (mg/dL)              | 1.04              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | Hemoglobin (g/dL)               | 14.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Hemoglobin (g/dL)               | 14.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Hemoglobin (g/dL)               | 14.3 (Mild)       | NOT RELATED                 | phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Hemoglobin (g/dL)               | 14.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Hemoglobin (g/dL)               | 14.0 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | PT (seconds)                    | 10.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | PTT (seconds)                   | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | Platelets (10 <sup>3</sup> /uL) | 203               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 211               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 230               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 219               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 215               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | Serum Lipase (U/L)           | 44.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Serum Lipase (U/L)           | 62.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Serum Lipase (U/L)           | 67.0 (Mild)       | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Serum Lipase (U/L)           | 52.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Serum Lipase (U/L)           | 53.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | WBC (10 <sup>3</sup> /uL)    | 4.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 4.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)    | 4.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 3.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP061  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 3.20 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | Alkaline Phosphatase (U/L)     | 42                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 45                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Alkaline Phosphatase (U/L)     | 50                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Alkaline Phosphatase (U/L)     | 52                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | Creatinine (mg/dL)               | 0.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Creatinine (mg/dL)               | 0.74              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Creatinine (mg/dL)               | 0.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Creatinine (mg/dL)               | 0.71              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Creatinine (mg/dL)               | 0.74              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | Hemoglobin (g/dL)               | 13.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Hemoglobin (g/dL)               | 13.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Hemoglobin (g/dL)               | 13.5 (Mild)       | NOT RELATED                 | phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Hemoglobin (g/dL)               | 13.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Hemoglobin (g/dL)               | 13.6 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | PT (seconds)                    | 9.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | PTT (seconds)                   | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | Platelets (10 <sup>3</sup> /uL) | 276               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 273               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 282               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 311               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 303               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | Serum Lipase (U/L)              | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Serum Lipase (U/L)           | 35.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Serum Lipase (U/L)           | 34.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Serum Lipase (U/L)           | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Serum Lipase (U/L)           | 38.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | -1                | -17              | WBC (10 <sup>3</sup> /uL)    | 7.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 5.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)    | 6.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | WBC (10 <sup>3</sup> /uL)    | 6.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP062  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 6.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | Alanine Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | Alkaline Phosphatase (U/L)     | 95                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 87                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Alkaline Phosphatase (U/L)     | 90                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Alkaline Phosphatase (U/L)     | 134               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Alkaline Phosphatase (U/L)     | 120               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | Creatinine (mg/dL)               | 0.82              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Creatinine (mg/dL)               | 0.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Creatinine (mg/dL)               | 0.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Creatinine (mg/dL)               | 0.74              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Creatinine (mg/dL)               | 0.75              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | Hemoglobin (g/dL)                | 15.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Hemoglobin (g/dL)               | 15.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Hemoglobin (g/dL)               | 14.8 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Hemoglobin (g/dL)               | 15.1 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Hemoglobin (g/dL)               | 14.8 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | PT (seconds)                    | 10.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | PTT (seconds)                   | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | Platelets (10 <sup>3</sup> /uL) | 207               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 213               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 228               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 232               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 217               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | Serum Lipase (U/L)              | 55.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Serum Lipase (U/L)              | 52.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Serum Lipase (U/L)           | 38.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Serum Lipase (U/L)           | 55.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Serum Lipase (U/L)           | 55.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | Total Bilirubin (mg/dL)      | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | WBC (10 <sup>3</sup> /uL)    | 6.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 5.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)    | 7.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | WBC (10 <sup>3</sup> /uL)    | 5.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP063  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | WBC (10 <sup>3</sup> /uL)    | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | -1                | -22              | Alanine Aminotransferase (U/L)   | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 8                 | 9                | Alanine Aminotransferase (U/L)   | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 29                | 28               | Alanine Aminotransferase (U/L)   | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 36                | 35               | Alanine Aminotransferase (U/L)   | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | -1                | -22              | Alkaline Phosphatase (U/L)       | 60                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 8                 | 9                | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 29                | 28               | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 36                | 35               | Alkaline Phosphatase (U/L)       | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | -1                | -22              | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 29                | 28               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 36                | 35               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | -1                | -22              | Creatinine (mg/dL)               | 0.83              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 1                 | 1                | Creatinine (mg/dL)               | 0.86              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 8                 | 9                | Creatinine (mg/dL)               | 0.87              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 29                | 28               | Creatinine (mg/dL)               | 0.82              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 36                | 35               | Creatinine (mg/dL)               | 0.84              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | -1                | -22              | Hemoglobin (g/dL)                | 13.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 1                 | 1                | Hemoglobin (g/dL)                | 13.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 8                 | 9                | Hemoglobin (g/dL)               | 13.1 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 29                | 28               | Hemoglobin (g/dL)               | 13.3 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 36                | 35               | Hemoglobin (g/dL)               | 12.6 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | -1                | -22              | PT (seconds)                    | 9.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | -1                | -22              | PTT (seconds)                   | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | -1                | -22              | Platelets (10 <sup>3</sup> /uL) | 442               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | -1                | -15              | Platelets (10 <sup>3</sup> /uL) | 389               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 362               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 363               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 29                | 28               | Platelets (10 <sup>3</sup> /uL) | 366               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 371               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | -1                | -22              | Serum Lipase (U/L)              | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 1                 | 1                | Serum Lipase (U/L)              | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 8                 | 9                | Serum Lipase (U/L)           | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 29                | 28               | Serum Lipase (U/L)           | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 36                | 35               | Serum Lipase (U/L)           | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | -1                | -22              | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 8                 | 9                | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 29                | 28               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 36                | 35               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | -1                | -22              | WBC (10 <sup>3</sup> /uL)    | 5.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 5.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)    | 6.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 29                | 28               | WBC (10 <sup>3</sup> /uL)    | 5.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP064  | 100 µg (≥71 years) | FEMALE | 75          | 36                | 35               | WBC (10 <sup>3</sup> /uL)    | 5.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | Alanine Aminotransferase (U/L)   | 38                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 35                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Alanine Aminotransferase (U/L)   | 33                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Alanine Aminotransferase (U/L)   | 45                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Alanine Aminotransferase (U/L)   | 32                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | Alkaline Phosphatase (U/L)       | 92                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 83                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Alkaline Phosphatase (U/L)       | 82                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Alkaline Phosphatase (U/L)       | 96                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Alkaline Phosphatase (U/L)       | 75                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | Aspartate Aminotransferase (U/L) | 28                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 28                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Aspartate Aminotransferase (U/L) | 31                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Aspartate Aminotransferase (U/L) | 27                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | Creatinine (mg/dL)               | 0.78              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Creatinine (mg/dL)               | 0.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Creatinine (mg/dL)               | 0.74              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Creatinine (mg/dL)               | 0.76              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Creatinine (mg/dL)               | 0.92              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | Hemoglobin (g/dL)                | 14.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Hemoglobin (g/dL)                | 13.5 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Hemoglobin (g/dL)               | 13.1 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Hemoglobin (g/dL)               | 14.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Hemoglobin (g/dL)               | 14.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | PT (seconds)                    | 10.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | PTT (seconds)                   | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | Platelets (10 <sup>3</sup> /uL) | 151               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 153               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 188               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 178               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 181               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | Serum Lipase (U/L)              | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Serum Lipase (U/L)              | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Serum Lipase (U/L)              | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Serum Lipase (U/L)             | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Serum Lipase (U/L)             | 23.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | Total Bilirubin (mg/dL)        | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | Total Bilirubin (mg/dL)        | 1.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | Total Bilirubin (mg/dL)        | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | -1                | -14              | WBC (10 <sup>3</sup> /uL)      | 4.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 3.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)      | 5.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 4.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP065  | 25 µg (≥71 years) | MALE | 72          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | -1                | -14              | Alanine Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 27                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 8                 | 9                | Alanine Aminotransferase (U/L)   | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 29                | 29               | Alanine Aminotransferase (U/L)   | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 36                | 37               | Alanine Aminotransferase (U/L)   | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | -1                | -14              | Alkaline Phosphatase (U/L)       | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 8                 | 9                | Alkaline Phosphatase (U/L)       | 48                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 29                | 29               | Alkaline Phosphatase (U/L)       | 48                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 36                | 37               | Alkaline Phosphatase (U/L)       | 47                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | -1                | -14              | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 29                | 29               | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 36                | 37               | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | -1                | -14              | Creatinine (mg/dL)               | 1.04              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 1                 | 1                | Creatinine (mg/dL)               | 1.07              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 8                 | 9                | Creatinine (mg/dL)               | 0.98              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 29                | 29               | Creatinine (mg/dL)               | 1.02              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 36                | 37               | Creatinine (mg/dL)               | 0.97              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | -1                | -14              | Hemoglobin (g/dL)                | 14.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 1                 | 1                | Hemoglobin (g/dL)                | 14.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 8                 | 9                | Hemoglobin (g/dL)                | 13.8 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 29                | 29               | Hemoglobin (g/dL)                | 14.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 36                | 37               | Hemoglobin (g/dL)               | 14.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | -1                | -14              | PT (seconds)                    | 11.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | -1                | -14              | PTT (seconds)                   | 31.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | -1                | -14              | Platelets (10 <sup>3</sup> /uL) | 201               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 165               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 176               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 156               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 177               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | -1                | -14              | Serum Lipase (U/L)              | 37.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 1                 | 1                | Serum Lipase (U/L)              | 34.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 8                 | 9                | Serum Lipase (U/L)              | 40.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 29                | 29               | Serum Lipase (U/L)              | 37.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years) | MALE | 73          | 36                | 37               | Serum Lipase (U/L)              | 43.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP066  | 25 µg (≥71 years)  | MALE   | 73          | -1                | -14              | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years)  | MALE   | 73          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years)  | MALE   | 73          | 8                 | 9                | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years)  | MALE   | 73          | 29                | 29               | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years)  | MALE   | 73          | 36                | 37               | Total Bilirubin (mg/dL)        | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years)  | MALE   | 73          | -1                | -14              | WBC (10 <sup>3</sup> /uL)      | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years)  | MALE   | 73          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 4.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years)  | MALE   | 73          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)      | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years)  | MALE   | 73          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 3.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP066  | 25 µg (≥71 years)  | MALE   | 73          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 4.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -15              | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Alanine Aminotransferase (U/L)   | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Alanine Aminotransferase (U/L)   | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 36               | Alanine Aminotransferase (U/L)   | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -15              | Alkaline Phosphatase (U/L)       | 77                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 71                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Alkaline Phosphatase (U/L)       | 64                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Alkaline Phosphatase (U/L)       | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 36               | Alkaline Phosphatase (U/L)       | 68                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -15              | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 36               | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -15              | Creatinine (mg/dL)               | 0.88              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Creatinine (mg/dL)               | 0.87              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Creatinine (mg/dL)               | 0.86              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Creatinine (mg/dL)               | 0.88              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 36               | Creatinine (mg/dL)               | 0.93              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -15              | Hemoglobin (g/dL)                | 11.9 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Hemoglobin (g/dL)                | 12.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Hemoglobin (g/dL)                | 12.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Hemoglobin (g/dL)                | 11.6 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 36               | Hemoglobin (g/dL)                | 11.7 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -15              | PT (seconds)                    | 10.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -15              | PTT (seconds)                   | 31.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -15              | Platelets (10 <sup>3</sup> /uL) | 219               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 191               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 200               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 202               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 191               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -15              | Serum Lipase (U/L)              | 40.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Serum Lipase (U/L)              | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Serum Lipase (U/L)              | 67.0 (Mild)       | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Serum Lipase (U/L)              | 46.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 36               | Serum Lipase (U/L)              | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -15              | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 36               | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -15              | WBC (10 <sup>3</sup> /uL)      | 5.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 3.50 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)      | 3.30 (Mild)       | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 3.30 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP067  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 3.40 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP068  | 25 µg (≥71 years)  | FEMALE | 73          | -1                | -15              | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years)  | FEMALE | 73          | 1                 | 1                | Alanine Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years)  | FEMALE | 73          | 8                 | 9                | Alanine Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Alanine Aminotransferase (U/L)   | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 36                | 37               | Alanine Aminotransferase (U/L)   | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | -1                | -15              | Alkaline Phosphatase (U/L)       | 66                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 70                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Alkaline Phosphatase (U/L)       | 62                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Alkaline Phosphatase (U/L)       | 64                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 36                | 37               | Alkaline Phosphatase (U/L)       | 68                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | -1                | -15              | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 36                | 37               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | -1                | -15              | Creatinine (mg/dL)               | 0.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Creatinine (mg/dL)               | 0.58              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Creatinine (mg/dL)               | 0.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Creatinine (mg/dL)               | 0.61              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 36                | 37               | Creatinine (mg/dL)               | 0.64              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | -1                | -15              | Hemoglobin (g/dL)                | 13.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Hemoglobin (g/dL)                | 14.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Hemoglobin (g/dL)                | 14.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Hemoglobin (g/dL)                | 14.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 36                | 37               | Hemoglobin (g/dL)                | 14.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | -1                | -15              | PT (seconds)                     | 10.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | -1                | -15              | PTT (seconds)                    | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | -1                | -15              | Platelets (10 <sup>3</sup> /uL) | 154               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 142               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 152               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 137 (Mild)        | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 150               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | -1                | -15              | Serum Lipase (U/L)              | 51.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Serum Lipase (U/L)              | 39.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Serum Lipase (U/L)              | 40.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Serum Lipase (U/L)              | 31.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 36                | 37               | Serum Lipase (U/L)              | 31.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | -1                | -15              | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 36                | 37               | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | -1                | -15              | WBC (10 <sup>3</sup> /uL)      | 6.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 6.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)      | 6.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 4.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP068  | 25 µg (≥71 years) | FEMALE | 73          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 4.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE   | 73          | -1                | -15              | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE   | 73          | 1                 | 1                | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE   | 73          | 8                 | 9                | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE   | 73          | 29                | 29               | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 36                | 37               | Alanine Aminotransferase (U/L)   | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | -1                | -15              | Alkaline Phosphatase (U/L)       | 45                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 48                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 8                 | 9                | Alkaline Phosphatase (U/L)       | 40                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 29                | 29               | Alkaline Phosphatase (U/L)       | 44                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 36                | 37               | Alkaline Phosphatase (U/L)       | 46                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | -1                | -15              | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 29                | 29               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 36                | 37               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | -1                | -15              | Creatinine (mg/dL)              | 0.98              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 1                 | 1                | Creatinine (mg/dL)              | 0.85              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 8                 | 9                | Creatinine (mg/dL)              | 0.87              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 29                | 29               | Creatinine (mg/dL)              | 0.88              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 36                | 37               | Creatinine (mg/dL)              | 0.93              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | -1                | -15              | Hemoglobin (g/dL)               | 13.5 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 1                 | 1                | Hemoglobin (g/dL)               | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 8                 | 9                | Hemoglobin (g/dL)               | 12.9 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 29                | 29               | Hemoglobin (g/dL)               | 13.3 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 36                | 37               | Hemoglobin (g/dL)               | 13.5 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | -1                | -15              | PT (seconds)                    | 10.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | -1                | -15              | PTT (seconds)                   | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | -1                | -15              | Platelets (10 <sup>3</sup> /uL) | 366               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 333               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 354               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 354               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 378               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | -1                | -15              | Serum Lipase (U/L)              | 33.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 1                 | 1                | Serum Lipase (U/L)              | 34.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 8                 | 9                | Serum Lipase (U/L)              | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 29                | 29               | Serum Lipase (U/L)              | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 36                | 37               | Serum Lipase (U/L)              | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | -1                | -15              | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 8                 | 9                | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years) | MALE | 73          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP069  | 25 µg (≥71 years)  | MALE   | 73          | 36                | 37               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years)  | MALE   | 73          | -1                | -15              | WBC (10 <sup>3</sup> /uL)      | 6.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years)  | MALE   | 73          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years)  | MALE   | 73          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)      | 6.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years)  | MALE   | 73          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 5.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP069  | 25 µg (≥71 years)  | MALE   | 73          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 5.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -21              | Alanine Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Alanine Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 28               | Alanine Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 35               | Alanine Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -21              | Alkaline Phosphatase (U/L)       | 51                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 58                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 51                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 28               | Alkaline Phosphatase (U/L)       | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 35               | Alkaline Phosphatase (U/L)       | 60                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -21              | Aspartate Aminotransferase (U/L) | 27                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 26                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 28               | Aspartate Aminotransferase (U/L) | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 35               | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -21              | Creatinine (mg/dL)               | 0.64              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Creatinine (mg/dL)              | 0.55              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Creatinine (mg/dL)              | 0.64              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 28               | Creatinine (mg/dL)              | 0.53              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 35               | Creatinine (mg/dL)              | 0.59              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -21              | Hemoglobin (g/dL)               | 12.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Hemoglobin (g/dL)               | 12.0 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Hemoglobin (g/dL)               | 12.0 (Mild)       | NOT RELATED                 | phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 28               | Hemoglobin (g/dL)               | 12.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 35               | Hemoglobin (g/dL)               | 12.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -21              | PT (seconds)                    | 10.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -21              | PTT (seconds)                   | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -21              | Platelets (10 <sup>3</sup> /uL) | 204               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 189               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 213               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 28               | Platelets (10 <sup>3</sup> /uL) | 200               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 201               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -21              | Serum Lipase (U/L)              | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Serum Lipase (U/L)              | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Serum Lipase (U/L)              | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 28               | Serum Lipase (U/L)              | 33.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 35               | Serum Lipase (U/L)              | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -21              | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 28               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 35               | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -21              | WBC (10 <sup>3</sup> /uL)      | 3.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -15              | WBC (10 <sup>3</sup> /uL)      | 4.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 3.10 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 3.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 28               | WBC (10 <sup>3</sup> /uL)      | 3.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP071  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 3.20 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP072  | 25 µg (≥71 years)  | MALE   | 71          | -1                | -13              | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years)  | MALE   | 71          | 1                 | 1                | Alanine Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years)  | MALE   | 71          | 8                 | 9                | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years)  | MALE   | 71          | 29                | 29               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years)  | MALE   | 71          | 36                | 37               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | -1                | -13              | Alkaline Phosphatase (U/L)       | 57                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 58                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 8                 | 9                | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 29                | 29               | Alkaline Phosphatase (U/L)       | 62                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 36                | 37               | Alkaline Phosphatase (U/L)       | 56                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | -1                | -13              | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 29                | 29               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 36                | 37               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | -1                | -13              | Creatinine (mg/dL)               | 1.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 1                 | 1                | Creatinine (mg/dL)              | 1.11              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 8                 | 9                | Creatinine (mg/dL)              | 1.07              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 29                | 29               | Creatinine (mg/dL)              | 1.15              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 36                | 37               | Creatinine (mg/dL)              | 1.06              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | -1                | -13              | Hemoglobin (g/dL)               | 14.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 1                 | 1                | Hemoglobin (g/dL)               | 13.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 8                 | 9                | Hemoglobin (g/dL)               | 13.0 (Mild)       | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 29                | 29               | Hemoglobin (g/dL)               | 14.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 36                | 37               | Hemoglobin (g/dL)               | 14.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | -1                | -13              | PT (seconds)                    | 9.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | -1                | -13              | PTT (seconds)                   | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | -1                | -13              | Platelets (10 <sup>3</sup> /uL) | 204               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 196               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 208               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 212               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 211               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | -1                | -13              | Serum Lipase (U/L)              | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 1                 | 1                | Serum Lipase (U/L)              | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 8                 | 9                | Serum Lipase (U/L)              | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 29                | 29               | Serum Lipase (U/L)              | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 36                | 37               | Serum Lipase (U/L)              | 23.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | -1                | -13              | Total Bilirubin (mg/dL)         | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 8                 | 9                | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years) | MALE | 71          | 36                | 37               | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP072  | 25 µg (≥71 years)  | MALE   | 71          | -1                | -13              | WBC (10 <sup>3</sup> /uL)      | 5.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years)  | MALE   | 71          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years)  | MALE   | 71          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)      | 6.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years)  | MALE   | 71          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 5.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP072  | 25 µg (≥71 years)  | MALE   | 71          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 5.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -13              | Alanine Aminotransferase (U/L) | 28                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Alanine Aminotransferase (U/L) | 28                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Alanine Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Alanine Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 37               | Alanine Aminotransferase (U/L) | 26                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -13              | Alkaline Phosphatase (U/L)     | 58                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 63                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Alkaline Phosphatase (U/L)       | 50                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Alkaline Phosphatase (U/L)       | 56                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 37               | Alkaline Phosphatase (U/L)       | 58                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -13              | Aspartate Aminotransferase (U/L) | 27                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 37               | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -13              | Creatinine (mg/dL)               | 0.79              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Creatinine (mg/dL)               | 0.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Creatinine (mg/dL)              | 0.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Creatinine (mg/dL)              | 0.73              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 37               | Creatinine (mg/dL)              | 0.76              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -13              | Hemoglobin (g/dL)               | 13.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Hemoglobin (g/dL)               | 13.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Hemoglobin (g/dL)               | 12.7 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Hemoglobin (g/dL)               | 12.6 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 37               | Hemoglobin (g/dL)               | 12.9 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -13              | PT (seconds)                    | 9.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -13              | PTT (seconds)                   | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -13              | Platelets (10 <sup>3</sup> /uL) | 171               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 187               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Platelets (10 <sup>3</sup> /uL) | 183               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 165               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 210               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -13              | Serum Lipase (U/L)              | 20.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Serum Lipase (U/L)              | 31.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Serum Lipase (U/L)              | 19.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Serum Lipase (U/L)              | 19.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 37               | Serum Lipase (U/L)              | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -13              | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 37               | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -13              | WBC (10 <sup>3</sup> /uL)       | 4.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 4.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 9                | WBC (10 <sup>3</sup> /uL)      | 4.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP073  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 4.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -19              | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 29               | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 36               | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -19              | Alkaline Phosphatase (U/L)     | 84                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 70                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 71                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 29               | Alkaline Phosphatase (U/L)       | 86                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 36               | Alkaline Phosphatase (U/L)       | 92                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -19              | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 29               | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 36               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -19              | Creatinine (mg/dL)               | 0.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Creatinine (mg/dL)               | 0.64              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Creatinine (mg/dL)               | 0.65              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 29               | Creatinine (mg/dL)              | 0.62              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 36               | Creatinine (mg/dL)              | 0.62              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -19              | Hemoglobin (g/dL)               | 13.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Hemoglobin (g/dL)               | 12.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Hemoglobin (g/dL)               | 12.3 (Mild)       | NOT RELATED                 | phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 29               | Hemoglobin (g/dL)               | 12.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 36               | Hemoglobin (g/dL)               | 12.3 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -19              | PT (seconds)                    | 9.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -19              | PTT (seconds)                   | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -19              | Platelets (10 <sup>3</sup> /uL) | 356               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 369               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 357               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 384               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 391               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -19              | Serum Lipase (U/L)              | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Serum Lipase (U/L)              | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Serum Lipase (U/L)              | 20.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 29               | Serum Lipase (U/L)              | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 36               | Serum Lipase (U/L)              | 38.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -19              | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 29               | Total Bilirubin (mg/dL)         | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 36               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -19              | WBC (10 <sup>3</sup> /uL)       | 5.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)       | 6.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 7.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 8.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP075  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 5.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE   | 73          | -1                | -20              | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE   | 73          | 1                 | 1                | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE   | 73          | 8                 | 8                | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE   | 73          | 29                | 28               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE   | 73          | 36                | 35               | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE   | 73          | -1                | -20              | Alkaline Phosphatase (U/L)     | 44                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE   | 73          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 43                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE   | 73          | 8                 | 8                | Alkaline Phosphatase (U/L)     | 42                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 29                | 28               | Alkaline Phosphatase (U/L)       | 41                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 36                | 35               | Alkaline Phosphatase (U/L)       | 51                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | -1                | -20              | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 28                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 26                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 29                | 28               | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 36                | 35               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | -1                | -20              | Creatinine (mg/dL)               | 1.03              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 1                 | 1                | Creatinine (mg/dL)               | 1.01              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 8                 | 8                | Creatinine (mg/dL)               | 1.07              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 29                | 28               | Creatinine (mg/dL)               | 1.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 36                | 35               | Creatinine (mg/dL)              | 1.06              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | -1                | -20              | Hemoglobin (g/dL)               | 13.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 1                 | 1                | Hemoglobin (g/dL)               | 14.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 8                 | 8                | Hemoglobin (g/dL)               | 13.7 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 29                | 28               | Hemoglobin (g/dL)               | 14.1 (Mild)       | NOT RELATED                 | phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 36                | 35               | Hemoglobin (g/dL)               | 14.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | -1                | -20              | PT (seconds)                    | 10.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | -1                | -20              | PTT (seconds)                   | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | -1                | -20              | Platelets (10 <sup>3</sup> /uL) | 195               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 186               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 194               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 29                | 28               | Platelets (10 <sup>3</sup> /uL) | 188               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 201               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | -1                | -20              | Serum Lipase (U/L)           | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 1                 | 1                | Serum Lipase (U/L)           | 20.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 8                 | 8                | Serum Lipase (U/L)           | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 29                | 28               | Serum Lipase (U/L)           | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 36                | 35               | Serum Lipase (U/L)           | 23.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | -1                | -20              | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 8                 | 8                | Total Bilirubin (mg/dL)      | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 29                | 28               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 36                | 35               | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | -1                | -20              | WBC (10 <sup>3</sup> /uL)    | 5.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 4.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE | 73          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)    | 5.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP076  | 100 µg (≥71 years) | MALE   | 73          | 29                | 28               | WBC (10 <sup>3</sup> /uL)      | 4.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP076  | 100 µg (≥71 years) | MALE   | 73          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 4.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -20              | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 28               | Alanine Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 35               | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -20              | Alkaline Phosphatase (U/L)     | 51                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Alkaline Phosphatase (U/L)     | 48                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 28               | Alkaline Phosphatase (U/L)     | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 35               | Alkaline Phosphatase (U/L)       | 47                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -20              | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 28               | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 35               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -20              | Creatinine (mg/dL)               | 0.73              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Creatinine (mg/dL)               | 0.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Creatinine (mg/dL)               | 0.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 28               | Creatinine (mg/dL)               | 0.66              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 35               | Creatinine (mg/dL)               | 0.71              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -20              | Hemoglobin (g/dL)               | 11.7 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Hemoglobin (g/dL)               | 11.7 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Hemoglobin (g/dL)               | 11.0 (Mild)       | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 28               | Hemoglobin (g/dL)               | 12.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 35               | Hemoglobin (g/dL)               | 11.7 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -20              | PT (seconds)                    | 10.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -20              | PTT (seconds)                   | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -20              | Platelets (10 <sup>3</sup> /uL) | 242               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 257               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 234               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 28               | Platelets (10 <sup>3</sup> /uL) | 252               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 224               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -20              | Serum Lipase (U/L)              | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Serum Lipase (U/L)           | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Serum Lipase (U/L)           | 33.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 28               | Serum Lipase (U/L)           | 36.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 35               | Serum Lipase (U/L)           | 33.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -20              | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 28               | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 35               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | -1                | -20              | WBC (10 <sup>3</sup> /uL)    | 5.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 5.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)    | 6.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 29                | 28               | WBC (10 <sup>3</sup> /uL)    | 6.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP077  | 100 µg (≥71 years) | FEMALE | 72          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 5.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -19              | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 8                | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 36               | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -19              | Alkaline Phosphatase (U/L)     | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 48                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 8                | Alkaline Phosphatase (U/L)     | 52                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Alkaline Phosphatase (U/L)     | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 36               | Alkaline Phosphatase (U/L)     | 61                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -19              | Aspartate Aminotransferase (U/L) | 27                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 36               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -19              | Creatinine (mg/dL)               | 0.71              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Creatinine (mg/dL)               | 0.69              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 8                | Creatinine (mg/dL)               | 0.69              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Creatinine (mg/dL)               | 0.64              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 36               | Creatinine (mg/dL)               | 0.61              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -19              | Hemoglobin (g/dL)                | 12.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Hemoglobin (g/dL)               | 12.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 8                | Hemoglobin (g/dL)               | 11.3 (Mild)       | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Hemoglobin (g/dL)               | 12.2 (Mild)       | NOT RELATED                 | phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 36               | Hemoglobin (g/dL)               | 11.9 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -19              | PT (seconds)                    | 9.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -19              | PTT (seconds)                   | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -19              | Platelets (10 <sup>3</sup> /uL) | 281               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 318               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 303               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Platelets (10 <sup>3</sup> /uL) | 306               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 333               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -19              | Serum Lipase (U/L)              | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Serum Lipase (U/L)              | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 8                | Serum Lipase (U/L)           | 23.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Serum Lipase (U/L)           | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 36               | Serum Lipase (U/L)           | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -19              | Total Bilirubin (mg/dL)      | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | Total Bilirubin (mg/dL)      | 1.4 (Mild)        | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 8                | Total Bilirubin (mg/dL)      | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | Total Bilirubin (mg/dL)      | 1.1               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 36               | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | -1                | -19              | WBC (10 <sup>3</sup> /uL)    | 4.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 4.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)    | 4.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 29                | 29               | WBC (10 <sup>3</sup> /uL)    | 3.40 (Mild)       | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP078  | 100 µg (≥71 years) | FEMALE | 73          | 36                | 36               | WBC (10 <sup>3</sup> /uL)    | 3.50 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | -1                | -20              | Alanine Aminotransferase (U/L)   | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 8                 | 8                | Alanine Aminotransferase (U/L)   | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 29                | 28               | Alanine Aminotransferase (U/L)   | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 36                | 35               | Alanine Aminotransferase (U/L)   | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | -1                | -20              | Alkaline Phosphatase (U/L)       | 65                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 67                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 60                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 29                | 28               | Alkaline Phosphatase (U/L)       | 69                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 36                | 35               | Alkaline Phosphatase (U/L)       | 70                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | -1                | -20              | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 29                | 28               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 36                | 35               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | -1                | -20              | Creatinine (mg/dL)               | 1.05              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 1                 | 1                | Creatinine (mg/dL)               | 1.04              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 8                 | 8                | Creatinine (mg/dL)               | 1.09              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 29                | 28               | Creatinine (mg/dL)               | 1.07              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 36                | 35               | Creatinine (mg/dL)               | 1.09              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | -1                | -20              | Hemoglobin (g/dL)                | 15.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 1                 | 1                | Hemoglobin (g/dL)                | 15.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 8                 | 8                | Hemoglobin (g/dL)               | 15.1 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 29                | 28               | Hemoglobin (g/dL)               | 14.9 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 36                | 35               | Hemoglobin (g/dL)               | 14.8 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | -1                | -20              | PT (seconds)                    | 10.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | -1                | -20              | PTT (seconds)                   | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | -1                | -20              | Platelets (10 <sup>3</sup> /uL) | 211               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 213               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 213               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 29                | 28               | Platelets (10 <sup>3</sup> /uL) | 197               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 225               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | -1                | -20              | Serum Lipase (U/L)              | 35.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 1                 | 1                | Serum Lipase (U/L)              | 34.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 8                 | 8                | Serum Lipase (U/L)              | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 29                | 28               | Serum Lipase (U/L)             | 31.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 36                | 35               | Serum Lipase (U/L)             | 46.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | -1                | -20              | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 8                 | 8                | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 29                | 28               | Total Bilirubin (mg/dL)        | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 36                | 35               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | -1                | -20              | WBC (10 <sup>3</sup> /uL)      | 6.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 4.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 5.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 29                | 28               | WBC (10 <sup>3</sup> /uL)      | 4.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP081  | 100 µg (≥71 years) | MALE | 72          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | -1                | -18              | Alanine Aminotransferase (U/L) | 41                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 41                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 8                 | 8                | Alanine Aminotransferase (U/L)   | 35                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 29                | 29               | Alanine Aminotransferase (U/L)   | 39                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 36                | 36               | Alanine Aminotransferase (U/L)   | 34                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | -1                | -18              | Alkaline Phosphatase (U/L)       | 48                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 57                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 29                | 29               | Alkaline Phosphatase (U/L)       | 54                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 36                | 36               | Alkaline Phosphatase (U/L)       | 61                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | -1                | -18              | Aspartate Aminotransferase (U/L) | 35                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 30                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 29                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 29                | 29               | Aspartate Aminotransferase (U/L) | 28                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 36                | 36               | Aspartate Aminotransferase (U/L) | 28                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | -1                | -18              | Creatinine (mg/dL)               | 0.85              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 1                 | 1                | Creatinine (mg/dL)               | 0.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 8                 | 8                | Creatinine (mg/dL)               | 0.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 29                | 29               | Creatinine (mg/dL)               | 0.91              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 36                | 36               | Creatinine (mg/dL)               | 0.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | -1                | -18              | Hemoglobin (g/dL)                | 15.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 1                 | 1                | Hemoglobin (g/dL)                | 15.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 8                 | 8                | Hemoglobin (g/dL)                | 15.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 29                | 29               | Hemoglobin (g/dL)                | 15.3 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group  | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|--------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 36                | 36               | Hemoglobin (g/dL)               | 15.4 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | -1                | -18              | PT (seconds)                    | 9.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | -1                | -18              | PTT (seconds)                   | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | -1                | -18              | Platelets (10 <sup>3</sup> /uL) | 144               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 104 (Moderate)    | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 125 (Mild)        | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 141               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | -1                | -18              | Serum Lipase (U/L)              | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 1                 | 1                | Serum Lipase (U/L)              | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 8                 | 8                | Serum Lipase (U/L)              | 31.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 29                | 29               | Serum Lipase (U/L)              | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | 36                | 36               | Serum Lipase (U/L)              | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years) | MALE | 71          | -1                | -18              | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP085  | 100 µg (≥71 years)  | MALE | 71          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years)  | MALE | 71          | 8                 | 8                | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years)  | MALE | 71          | 29                | 29               | Total Bilirubin (mg/dL)        | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years)  | MALE | 71          | 36                | 36               | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years)  | MALE | 71          | -1                | -18              | WBC (10 <sup>3</sup> /uL)      | 6.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years)  | MALE | 71          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years)  | MALE | 71          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 6.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years)  | MALE | 71          | 29                | 29               | WBC (10 <sup>3</sup> /uL)      | 5.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP085  | 100 µg (≥71 years)  | MALE | 71          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 5.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | -1                | -13              | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 1                 | 1                | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 8                 | 8                | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 29                | 27               | Alanine Aminotransferase (U/L)   | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 36                | 34               | Alanine Aminotransferase (U/L)   | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | -1                | -13              | Alkaline Phosphatase (U/L)       | 54                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 56                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 29                | 27               | Alkaline Phosphatase (U/L)       | 46                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 36                | 34               | Alkaline Phosphatase (U/L)       | 48                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | -1                | -13              | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 29                | 27               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 36                | 34               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | -1                | -13              | Creatinine (mg/dL)               | 0.95              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 1                 | 1                | Creatinine (mg/dL)               | 1.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 8                 | 8                | Creatinine (mg/dL)               | 0.89              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 29                | 27               | Creatinine (mg/dL)               | 0.87              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 36                | 34               | Creatinine (mg/dL)               | 0.92              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | -1                | -13              | Hemoglobin (g/dL)                | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 1                 | 1                | Hemoglobin (g/dL)                | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 8                 | 8                | Hemoglobin (g/dL)                | 14.2 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 29                | 27               | Hemoglobin (g/dL)                | 13.7 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | 36                | 34               | Hemoglobin (g/dL)                | 13.5 (Mild)       | NOT RELATED                 | phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | -1                | -13              | PT (seconds)                     | 10.4              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE | 35          | -1                | -13              | PTT (seconds)                    | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP092  | 50 µg<br>(18-55 years) | MALE | 35          | -1                | -13              | Platelets (10 <sup>3</sup> /uL) | 246               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg<br>(18-55 years) | MALE | 35          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 230               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg<br>(18-55 years) | MALE | 35          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 210               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg<br>(18-55 years) | MALE | 35          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 188               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg<br>(18-55 years) | MALE | 35          | 36                | 34               | Platelets (10 <sup>3</sup> /uL) | 223               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg<br>(18-55 years) | MALE | 35          | -1                | -13              | Serum Lipase (U/L)              | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg<br>(18-55 years) | MALE | 35          | 1                 | 1                | Serum Lipase (U/L)              | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg<br>(18-55 years) | MALE | 35          | 8                 | 8                | Serum Lipase (U/L)              | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg<br>(18-55 years) | MALE | 35          | 29                | 27               | Serum Lipase (U/L)              | 19.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg<br>(18-55 years) | MALE | 35          | 36                | 34               | Serum Lipase (U/L)              | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg<br>(18-55 years) | MALE | 35          | -1                | -13              | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg<br>(18-55 years) | MALE | 35          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg<br>(18-55 years) | MALE | 35          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP092  | 50 µg (18-55 years) | MALE   | 35          | 29                | 27               | Total Bilirubin (mg/dL)        | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE   | 35          | 36                | 34               | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE   | 35          | -1                | -13              | WBC (10 <sup>3</sup> /uL)      | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE   | 35          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 4.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE   | 35          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE   | 35          | 29                | 27               | WBC (10 <sup>3</sup> /uL)      | 3.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP092  | 50 µg (18-55 years) | MALE   | 35          | 36                | 34               | WBC (10 <sup>3</sup> /uL)      | 4.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | -1                | -9               | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 1                 | 1                | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 8                 | 8                | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 29                | 27               | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 36                | 34               | Alanine Aminotransferase (U/L)   | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | -1                | -9               | Alkaline Phosphatase (U/L)       | 48                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 44                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 29                | 27               | Alkaline Phosphatase (U/L)       | 44                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 36                | 34               | Alkaline Phosphatase (U/L)       | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | -1                | -9               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 29                | 27               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 36                | 34               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | -1                | -9               | Creatinine (mg/dL)              | 0.85              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 1                 | 1                | Creatinine (mg/dL)              | 0.91              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 8                 | 8                | Creatinine (mg/dL)              | 0.89              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 29                | 27               | Creatinine (mg/dL)              | 0.82              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 36                | 34               | Creatinine (mg/dL)              | 0.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | -1                | -9               | Hemoglobin (g/dL)               | 14.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 1                 | 1                | Hemoglobin (g/dL)               | 14.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 8                 | 8                | Hemoglobin (g/dL)               | 12.8 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 29                | 27               | Hemoglobin (g/dL)               | 13.4 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | 36                | 34               | Hemoglobin (g/dL)               | 13.0 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | -1                | -9               | PT (seconds)                    | 10.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | -1                | -9               | PTT (seconds)                   | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg (18-55 years) | FEMALE | 54          | -1                | -9               | Platelets (10 <sup>3</sup> /uL) | 242               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 250               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 232               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 237               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | 36                | 34               | Platelets (10 <sup>3</sup> /uL) | 268               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | -1                | -9               | Serum Lipase (U/L)              | 55.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | 1                 | 1                | Serum Lipase (U/L)              | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | 8                 | 8                | Serum Lipase (U/L)              | 36.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | 29                | 27               | Serum Lipase (U/L)              | 49.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | 36                | 34               | Serum Lipase (U/L)              | 39.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | -1                | -9               | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | 29                | 27               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | 36                | 34               | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | -1                | -9               | WBC (10 <sup>3</sup> /uL)      | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 4.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 4.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | 29                | 27               | WBC (10 <sup>3</sup> /uL)      | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP094  | 50 µg<br>(18-55 years) | FEMALE | 54          | 36                | 34               | WBC (10 <sup>3</sup> /uL)      | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE   | 23          | -1                | -9               | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE   | 23          | 1                 | 1                | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE   | 23          | 8                 | 8                | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE   | 23          | 29                | 27               | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE   | 23          | 36                | 34               | Alanine Aminotransferase (U/L) | 8                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | -1                | -9               | Alkaline Phosphatase (U/L)       | 50                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 54                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 56                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 29                | 27               | Alkaline Phosphatase (U/L)       | 46                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 36                | 34               | Alkaline Phosphatase (U/L)       | 47                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | -1                | -9               | Aspartate Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 29                | 27               | Aspartate Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 36                | 34               | Aspartate Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | -1                | -9               | Creatinine (mg/dL)               | 0.89              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP095  | 50 µg (18-55 years) | MALE | 23          | 1                 | 1                | Creatinine (mg/dL)              | 0.98              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg (18-55 years) | MALE | 23          | 8                 | 8                | Creatinine (mg/dL)              | 0.97              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg (18-55 years) | MALE | 23          | 29                | 27               | Creatinine (mg/dL)              | 0.87              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg (18-55 years) | MALE | 23          | 36                | 34               | Creatinine (mg/dL)              | 0.86              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg (18-55 years) | MALE | 23          | -1                | -9               | Hemoglobin (g/dL)               | 14.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg (18-55 years) | MALE | 23          | 1                 | 1                | Hemoglobin (g/dL)               | 16.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg (18-55 years) | MALE | 23          | 8                 | 8                | Hemoglobin (g/dL)               | 15.5 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP095  | 50 µg (18-55 years) | MALE | 23          | 29                | 27               | Hemoglobin (g/dL)               | 16.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg (18-55 years) | MALE | 23          | 36                | 34               | Hemoglobin (g/dL)               | 14.8 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP095  | 50 µg (18-55 years) | MALE | 23          | -1                | -9               | PT (seconds)                    | 10.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg (18-55 years) | MALE | 23          | -1                | -9               | PTT (seconds)                   | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg (18-55 years) | MALE | 23          | -1                | -9               | Platelets (10 <sup>3</sup> /uL) | 259               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg (18-55 years) | MALE | 23          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 285               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 256               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 243               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 36                | 34               | Platelets (10 <sup>3</sup> /uL) | 266               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | -1                | -9               | Serum Lipase (U/L)              | 12.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 1                 | 1                | Serum Lipase (U/L)              | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 8                 | 8                | Serum Lipase (U/L)              | 23.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 29                | 27               | Serum Lipase (U/L)              | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 36                | 34               | Serum Lipase (U/L)              | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | -1                | -9               | Total Bilirubin (mg/dL)         | 1.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 1                 | 1                | Total Bilirubin (mg/dL)         | 1.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 29                | 27               | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg<br>(18-55 years) | MALE | 23          | 36                | 34               | Total Bilirubin (mg/dL)         | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP095  | 50 µg (18-55 years) | MALE | 23          | -1                | -9               | WBC (10 <sup>3</sup> /uL)      | 5.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg (18-55 years) | MALE | 23          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 6.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg (18-55 years) | MALE | 23          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 7.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg (18-55 years) | MALE | 23          | 29                | 27               | WBC (10 <sup>3</sup> /uL)      | 5.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP095  | 50 µg (18-55 years) | MALE | 23          | 36                | 34               | WBC (10 <sup>3</sup> /uL)      | 6.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | -1                | -9               | Alanine Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | 1                 | 1                | Alanine Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | 8                 | 8                | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | 29                | 27               | Alanine Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | 36                | 36               | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | -1                | -9               | Alkaline Phosphatase (U/L)     | 88                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 87                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 89                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 29                | 27               | Alkaline Phosphatase (U/L)       | 77                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 36                | 36               | Alkaline Phosphatase (U/L)       | 68                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | -1                | -9               | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 33                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 29                | 27               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 36                | 36               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | -1                | -9               | Creatinine (mg/dL)               | 0.76              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 1                 | 1                | Creatinine (mg/dL)               | 0.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 8                 | 8                | Creatinine (mg/dL)              | 0.77              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 29                | 27               | Creatinine (mg/dL)              | 0.72              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 36                | 36               | Creatinine (mg/dL)              | 0.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | -1                | -9               | Hemoglobin (g/dL)               | 15.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 1                 | 1                | Hemoglobin (g/dL)               | 14.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 8                 | 8                | Hemoglobin (g/dL)               | 14.0 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 29                | 27               | Hemoglobin (g/dL)               | 14.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 36                | 36               | Hemoglobin (g/dL)               | 13.3 (Mild)       | NOT RELATED                 | phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | -1                | -9               | PT (seconds)                    | 10.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | -1                | -9               | PTT (seconds)                   | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | -1                | -9               | Platelets (10 <sup>3</sup> /uL) | 239               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 212               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 210               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 232               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | 36                | 36               | Platelets (10 <sup>3</sup> /uL) | 235               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | -1                | -9               | Serum Lipase (U/L)              | 8.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | 1                 | 1                | Serum Lipase (U/L)              | 12.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | 8                 | 8                | Serum Lipase (U/L)              | 12.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | 29                | 27               | Serum Lipase (U/L)              | 12.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | 36                | 36               | Serum Lipase (U/L)              | 13.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | -1                | -9               | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | 29                | 27               | Total Bilirubin (mg/dL)         | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | 36                | 36               | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg (18-55 years) | MALE | 29          | -1                | -9               | WBC (10 <sup>3</sup> /uL)       | 5.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 6.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 29                | 27               | WBC (10 <sup>3</sup> /uL)      | 5.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP096  | 50 µg<br>(18-55 years) | MALE | 29          | 36                | 36               | WBC (10 <sup>3</sup> /uL)      | 6.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | -1                | -9               | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | 1                 | 1                | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | 8                 | 8                | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | 29                | 27               | Alanine Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | 36                | 34               | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | -1                | -9               | Alkaline Phosphatase (U/L)     | 67                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 63                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 65                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | 29                | 27               | Alkaline Phosphatase (U/L)       | 60                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | 36                | 34               | Alkaline Phosphatase (U/L)       | 60                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | -1                | -9               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | 29                | 27               | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | 36                | 34               | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | -1                | -9               | Creatinine (mg/dL)               | 0.79              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | 1                 | 1                | Creatinine (mg/dL)               | 0.85              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | 8                 | 8                | Creatinine (mg/dL)               | 0.79              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | 29                | 27               | Creatinine (mg/dL)              | 0.82              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | 36                | 34               | Creatinine (mg/dL)              | 0.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | -1                | -9               | Hemoglobin (g/dL)               | 14.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | 1                 | 1                | Hemoglobin (g/dL)               | 14.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | 8                 | 8                | Hemoglobin (g/dL)               | 13.9 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | 29                | 27               | Hemoglobin (g/dL)               | 15.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | 36                | 34               | Hemoglobin (g/dL)               | 13.8 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | -1                | -9               | PT (seconds)                    | 9.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | -1                | -9               | PTT (seconds)                   | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | -1                | -9               | Platelets (10 <sup>3</sup> /uL) | 212               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 211               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 208               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE | 31          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 244               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | 36                | 34               | Platelets (10 <sup>3</sup> /uL) | 235               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | -1                | -9               | Serum Lipase (U/L)              | 20.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | 1                 | 1                | Serum Lipase (U/L)              | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | 8                 | 8                | Serum Lipase (U/L)              | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | 29                | 27               | Serum Lipase (U/L)              | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | 36                | 34               | Serum Lipase (U/L)              | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | -1                | -9               | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | 8                 | 8                | Total Bilirubin (mg/dL)         | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | 29                | 27               | Total Bilirubin (mg/dL)         | 1.1               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | 36                | 34               | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | -1                | -9               | WBC (10 <sup>3</sup> /uL)       | 5.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg<br>(18-55 years) | MALE | 31          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)       | 4.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP097  | 50 µg (18-55 years) | MALE   | 31          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 4.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE   | 31          | 29                | 27               | WBC (10 <sup>3</sup> /uL)      | 4.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP097  | 50 µg (18-55 years) | MALE   | 31          | 36                | 34               | WBC (10 <sup>3</sup> /uL)      | 4.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | -1                | -8               | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 1                 | 1                | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 8                 | 8                | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 29                | 27               | Alanine Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 36                | 34               | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | -1                | -8               | Alkaline Phosphatase (U/L)     | 48                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 43                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 8                 | 8                | Alkaline Phosphatase (U/L)     | 44                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 29                | 27               | Alkaline Phosphatase (U/L)       | 45                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 36                | 34               | Alkaline Phosphatase (U/L)       | 51                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | -1                | -8               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 29                | 27               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 36                | 34               | Aspartate Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | -1                | -8               | Creatinine (mg/dL)               | 0.83              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 1                 | 1                | Creatinine (mg/dL)               | 0.83              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 8                 | 8                | Creatinine (mg/dL)               | 0.82              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 29                | 27               | Creatinine (mg/dL)               | 0.71              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 36                | 34               | Creatinine (mg/dL)              | 0.84              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | -1                | -8               | Hemoglobin (g/dL)               | 14.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 1                 | 1                | Hemoglobin (g/dL)               | 13.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 8                 | 8                | Hemoglobin (g/dL)               | 13.5 (Mild)       | NOT RELATED                 | Phlebotomy                           | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 29                | 27               | Hemoglobin (g/dL)               | 13.7 (Mild)       | NOT RELATED                 | Phlebotomy                           | NA- NOT APPLICABLE                  | No                                  |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 36                | 34               | Hemoglobin (g/dL)               | 14.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | -1                | -8               | PT (seconds)                    | 10.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | -1                | -8               | PTT (seconds)                   | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | -1                | -8               | Platelets (10 <sup>3</sup> /uL) | 279               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 258               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 245               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 254               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 36                | 34               | Platelets (10 <sup>3</sup> /uL) | 248               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP098  | 50 µg<br>(18-55 years) | FEMALE | 43          | -1                | -8               | Serum Lipase (U/L)           | 11.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg<br>(18-55 years) | FEMALE | 43          | 1                 | 1                | Serum Lipase (U/L)           | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg<br>(18-55 years) | FEMALE | 43          | 8                 | 8                | Serum Lipase (U/L)           | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg<br>(18-55 years) | FEMALE | 43          | 29                | 27               | Serum Lipase (U/L)           | 10.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg<br>(18-55 years) | FEMALE | 43          | 36                | 34               | Serum Lipase (U/L)           | 20.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg<br>(18-55 years) | FEMALE | 43          | -1                | -8               | Total Bilirubin (mg/dL)      | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg<br>(18-55 years) | FEMALE | 43          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg<br>(18-55 years) | FEMALE | 43          | 8                 | 8                | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg<br>(18-55 years) | FEMALE | 43          | 29                | 27               | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg<br>(18-55 years) | FEMALE | 43          | 36                | 34               | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg<br>(18-55 years) | FEMALE | 43          | -1                | -8               | WBC (10 <sup>3</sup> /uL)    | 7.10              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg<br>(18-55 years) | FEMALE | 43          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 6.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg<br>(18-55 years) | FEMALE | 43          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)    | 7.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 29                | 27               | WBC (10 <sup>3</sup> /uL)      | 6.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP098  | 50 µg (18-55 years) | FEMALE | 43          | 36                | 34               | WBC (10 <sup>3</sup> /uL)      | 7.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE   | 39          | -1                | -8               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE   | 39          | -1                | -6               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE   | 39          | 1                 | 1                | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE   | 39          | 8                 | 8                | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE   | 39          | 29                | 27               | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE   | 39          | 36                | 34               | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE   | 39          | -1                | -8               | Alkaline Phosphatase (U/L)     | 50                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE   | 39          | -1                | -6               | Alkaline Phosphatase (U/L)     | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE   | 39          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 61                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | 8                 | 8                | Alkaline Phosphatase (U/L)       | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | 29                | 27               | Alkaline Phosphatase (U/L)       | 57                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | 36                | 34               | Alkaline Phosphatase (U/L)       | 57                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | -1                | -8               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | -1                | -6               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | 8                 | 8                | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | 29                | 27               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | 36                | 34               | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | -1                | -8               | Creatinine (mg/dL)               | 0.85              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | -1                | -6               | Creatinine (mg/dL)               | 0.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | 1                 | 1                | Creatinine (mg/dL)              | 0.87              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | 8                 | 8                | Creatinine (mg/dL)              | 0.79              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | 29                | 27               | Creatinine (mg/dL)              | 0.76              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | 36                | 34               | Creatinine (mg/dL)              | 0.82              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | -1                | -8               | Hemoglobin (g/dL)               | 13.4 (Mild)       | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | 1                 | 1                | Hemoglobin (g/dL)               | 14.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | 8                 | 8                | Hemoglobin (g/dL)               | 12.2 (Moderate)   | RELATED                     | N/A                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | 29                | 27               | Hemoglobin (g/dL)               | 13.0 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | 36                | 34               | Hemoglobin (g/dL)               | 13.1 (Mild)       | RELATED                     | N/A                                  | NA- NOT APPLICABLE                  | No                                  |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | -1                | -8               | PT (seconds)                    | 10.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | -1                | -8               | PTT (seconds)                   | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | -1                | -8               | Platelets (10 <sup>3</sup> /uL) | 229               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg (18-55 years) | MALE | 39          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 250               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | 8                 | 8                | Platelets (10 <sup>3</sup> /uL) | 239               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 221               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | 36                | 34               | Platelets (10 <sup>3</sup> /uL) | 245               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | -1                | -8               | Serum Lipase (U/L)              | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | 1                 | 1                | Serum Lipase (U/L)              | 23.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | 8                 | 8                | Serum Lipase (U/L)              | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | 29                | 27               | Serum Lipase (U/L)              | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | 36                | 34               | Serum Lipase (U/L)              | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | -1                | -8               | Total Bilirubin (mg/dL)         | 1.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | -1                | -6               | Total Bilirubin (mg/dL)         | 1.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | 1                 | 1                | Total Bilirubin (mg/dL)         | 1.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | 8                 | 8                | Total Bilirubin (mg/dL)         | 1.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | 29                | 27               | Total Bilirubin (mg/dL)         | 1.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | 36                | 34               | Total Bilirubin (mg/dL)        | 1.1               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | -1                | -8               | WBC (10 <sup>3</sup> /uL)      | 4.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | 8                 | 8                | WBC (10 <sup>3</sup> /uL)      | 4.70              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | 29                | 27               | WBC (10 <sup>3</sup> /uL)      | 4.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01KP101  | 50 µg<br>(18-55 years) | MALE | 39          | 36                | 34               | WBC (10 <sup>3</sup> /uL)      | 4.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg<br>(≥71 years)   | MALE | 74          | -1                | -39              | Alanine Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg<br>(≥71 years)   | MALE | 74          | 1                 | 1                | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg<br>(≥71 years)   | MALE | 74          | 8                 | 7                | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg<br>(≥71 years)   | MALE | 74          | 29                | 27               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg<br>(≥71 years)   | MALE | 74          | 36                | 35               | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | -1                | -39              | Alkaline Phosphatase (U/L)       | 52                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 50                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 29                | 27               | Alkaline Phosphatase (U/L)       | 47                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 36                | 35               | Alkaline Phosphatase (U/L)       | 49                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | -1                | -39              | Aspartate Aminotransferase (U/L) | 37                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 35                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 35                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 29                | 27               | Aspartate Aminotransferase (U/L) | 31                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 36                | 35               | Aspartate Aminotransferase (U/L) | 42                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | -1                | -39              | Creatinine (mg/dL)               | 0.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology            | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 1                 | 1                | Creatinine (mg/dL)              | 0.96              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 8                 | 7                | Creatinine (mg/dL)              | 0.94              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 29                | 27               | Creatinine (mg/dL)              | 0.97              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 36                | 35               | Creatinine (mg/dL)              | 0.96              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | -1                | -39              | Hemoglobin (g/dL)               | 15.7              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 1                 | 1                | Hemoglobin (g/dL)               | 14.7              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 8                 | 7                | Hemoglobin (g/dL)               | 14.5 (Mild)       | NOT RELATED                 | Hgb within institutional normal range           | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 29                | 27               | Hemoglobin (g/dL)               | 14.8              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 36                | 35               | Hemoglobin (g/dL)               | 14.3 (Mild)       | NOT RELATED                 | Hemoglobin is within institutional normal range | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | -1                | -39              | PT (seconds)                    | 13.3              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | -1                | -39              | PTT (seconds)                   | 32.0              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | -1                | -39              | Platelets (10 <sup>3</sup> /uL) | 216               | N/A                         | N/A   | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 196               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 219               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 209               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 222               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | -1                | -39              | Serum Lipase (U/L)              | 31.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 1                 | 1                | Serum Lipase (U/L)              | 31.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 8                 | 7                | Serum Lipase (U/L)              | 34.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 29                | 27               | Serum Lipase (U/L)              | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 36                | 35               | Serum Lipase (U/L)              | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | -1                | -39              | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 8                 | 7                | Total Bilirubin (mg/dL)         | 1.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years) | MALE | 74          | 29                | 27               | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR002  | 50 µg (≥71 years)   | MALE   | 74          | 36                | 35               | Total Bilirubin (mg/dL)        | 1.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years)   | MALE   | 74          | -1                | -39              | WBC (10 <sup>3</sup> /uL)      | 6.11              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years)   | MALE   | 74          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.05              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years)   | MALE   | 74          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 5.98              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years)   | MALE   | 74          | 29                | 27               | WBC (10 <sup>3</sup> /uL)      | 5.06              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR002  | 50 µg (≥71 years)   | MALE   | 74          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 7.37              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | -1                | -36              | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 1                 | 1                | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 8                 | 7                | Alanine Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 29                | 31               | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 36                | 37               | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | -1                | -36              | Alkaline Phosphatase (U/L)       | 68                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 69                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 66                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 29                | 31               | Alkaline Phosphatase (U/L)       | 69                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 36                | 37               | Alkaline Phosphatase (U/L)       | 66                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | -1                | -36              | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 29                | 31               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 36                | 37               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | -1                | -36              | Creatinine (mg/dL)               | 0.63              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology         | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--|-------------------------------------|-------------------------------------|
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 1                 | 1                | Creatinine (mg/dL)           | 0.67              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 8                 | 7                | Creatinine (mg/dL)           | 0.77              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 29                | 31               | Creatinine (mg/dL)           | 0.73              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 36                | 37               | Creatinine (mg/dL)           | 0.80              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | -1                | -36              | Hemoglobin (g/dL)            | 12.7              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 1                 | 1                | Hemoglobin (g/dL)            | 13.2              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 8                 | 7                | Hemoglobin (g/dL)            | 12.4 (Mild)       | NOT RELATED                 | Hgb within institutional normal range        | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 29                | 31               | Hemoglobin (g/dL)            | 12.4 (Mild)       | NOT RELATED                 | hemoglobin within institutional normal range | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 36                | 37               | Hemoglobin (g/dL)            | 12.3 (Mild)       | NOT RELATED                 | Hemoglobin within institutional normal range | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | -1                | -36              | PT (seconds)                 | 13.6              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | -1                | -36              | PTT (seconds)                | 32.8              | N/A                         | N/A  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | -1                | -36              | Platelets (10 <sup>3</sup> /uL) | 237               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 215               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 237               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 29                | 31               | Platelets (10 <sup>3</sup> /uL) | 248               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 275               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | -1                | -36              | Serum Lipase (U/L)              | 19.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 1                 | 1                | Serum Lipase (U/L)              | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 8                 | 7                | Serum Lipase (U/L)              | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 29                | 31               | Serum Lipase (U/L)              | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 36                | 37               | Serum Lipase (U/L)              | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | -1                | -36              | Total Bilirubin (mg/dL)         | 0.1               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 8                 | 7                | Total Bilirubin (mg/dL)         | 0.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 29                | 31               | Total Bilirubin (mg/dL)        | 0.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 36                | 37               | Total Bilirubin (mg/dL)        | 0.1               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | -1                | -36              | WBC (10 <sup>3</sup> /uL)      | 5.56              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 5.41              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 6.04              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 29                | 31               | WBC (10 <sup>3</sup> /uL)      | 5.91              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR003  | 50 µg (56-70 years) | FEMALE | 56          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 5.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE   | 63          | -1                | -37              | Alanine Aminotransferase (U/L) | 32                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE   | 63          | 1                 | 1                | Alanine Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE   | 63          | 8                 | 7                | Alanine Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE   | 63          | 29                | 27               | Alanine Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 36                | 33               | Alanine Aminotransferase (U/L)   | 31                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | -1                | -37              | Alkaline Phosphatase (U/L)       | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 29                | 27               | Alkaline Phosphatase (U/L)       | 52                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 36                | 33               | Alkaline Phosphatase (U/L)       | 57                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | -1                | -37              | Aspartate Aminotransferase (U/L) | 27                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 29                | 27               | Aspartate Aminotransferase (U/L) | 30                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 36                | 33               | Aspartate Aminotransferase (U/L) | 26                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology            | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | -1                | -37              | Creatinine (mg/dL)           | 1.03              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 1                 | 1                | Creatinine (mg/dL)           | 1.08              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 8                 | 7                | Creatinine (mg/dL)           | 1.14              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 29                | 27               | Creatinine (mg/dL)           | 1.15              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 36                | 33               | Creatinine (mg/dL)           | 1.03              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | -1                | -37              | Hemoglobin (g/dL)            | 15.1              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 1                 | 1                | Hemoglobin (g/dL)            | 15.4              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 8                 | 7                | Hemoglobin (g/dL)            | 14.8 (Mild)       | NOT RELATED                 | Hgb within institutional normal range           | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 29                | 27               | Hemoglobin (g/dL)            | 14.4 (Mild)       | NOT RELATED                 | hemoglobin within institutional normal range    | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 36                | 33               | Hemoglobin (g/dL)            | 15.0 (Mild)       | NOT RELATED                 | hemoglobin is within institutional normal range | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | -1                | -37              | PT (seconds)                 | 13.4              | N/A                         | N/A   | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | -1                | -37              | PTT (seconds)                   | 32.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | -1                | -37              | Platelets (10 <sup>3</sup> /uL) | 229               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 206               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 227               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 206               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 36                | 33               | Platelets (10 <sup>3</sup> /uL) | 223               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | -1                | -37              | Serum Lipase (U/L)              | 37.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 1                 | 1                | Serum Lipase (U/L)              | 31.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 8                 | 7                | Serum Lipase (U/L)              | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 29                | 27               | Serum Lipase (U/L)              | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 36                | 33               | Serum Lipase (U/L)              | 30.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | -1                | -37              | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 8                 | 7                | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 29                | 27               | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 36                | 33               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | -1                | -37              | WBC (10 <sup>3</sup> /uL)      | 7.20              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 7.12              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 7.63              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 29                | 27               | WBC (10 <sup>3</sup> /uL)      | 6.33              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR005  | 50 µg (56-70 years) | MALE | 63          | 36                | 33               | WBC (10 <sup>3</sup> /uL)      | 6.72              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | -1                | -35              | Alanine Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 1                 | 1                | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 8                 | 7                | Alanine Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 29                | 31               | Alanine Aminotransferase (U/L)   | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 36                | 37               | Alanine Aminotransferase (U/L)   | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | -1                | -35              | Alkaline Phosphatase (U/L)       | 82                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 80                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 80                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 29                | 31               | Alkaline Phosphatase (U/L)       | 82                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 36                | 37               | Alkaline Phosphatase (U/L)       | 78                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | -1                | -35              | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 29                | 31               | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology            | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 36                | 37               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | -1                | -35              | Creatinine (mg/dL)               | 1.00              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 1                 | 1                | Creatinine (mg/dL)               | 1.03              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 8                 | 7                | Creatinine (mg/dL)               | 1.02              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 29                | 31               | Creatinine (mg/dL)               | 1.05              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 36                | 37               | Creatinine (mg/dL)               | 1.08              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | -1                | -35              | Hemoglobin (g/dL)                | 15.6              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 1                 | 1                | Hemoglobin (g/dL)                | 15.4              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 8                 | 7                | Hemoglobin (g/dL)                | 15.2 (Mild)       | NOT RELATED                 | hgb within INR                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 29                | 31               | Hemoglobin (g/dL)                | 15.2 (Mild)       | NOT RELATED                 | hemoglobin within institutional normal range    | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 36                | 37               | Hemoglobin (g/dL)                | 14.9 (Mild)       | NOT RELATED                 | hemoglobin is within institutional normal range | NC- DOSE NOT CHANGED                | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 57                | 59               | Hemoglobin (g/dL)               | 15.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | -1                | -35              | PT (seconds)                    | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | -1                | -35              | PTT (seconds)                   | 30.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | -1                | -35              | Platelets (10 <sup>3</sup> /uL) | 174               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 153               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 160               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 29                | 31               | Platelets (10 <sup>3</sup> /uL) | 164               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 148               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 57                | 59               | Platelets (10 <sup>3</sup> /uL) | 170               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | -1                | -35              | Serum Lipase (U/L)              | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 1                 | 1                | Serum Lipase (U/L)              | 19.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 8                 | 7                | Serum Lipase (U/L)              | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg (56-70 years) | MALE | 65          | 29                | 31               | Serum Lipase (U/L)              | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR006  | 50 µg<br>(56-70 years) | MALE | 65          | 36                | 37               | Serum Lipase (U/L)             | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg<br>(56-70 years) | MALE | 65          | -1                | -35              | Total Bilirubin (mg/dL)        | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg<br>(56-70 years) | MALE | 65          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg<br>(56-70 years) | MALE | 65          | 8                 | 7                | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg<br>(56-70 years) | MALE | 65          | 29                | 31               | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg<br>(56-70 years) | MALE | 65          | 36                | 37               | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg<br>(56-70 years) | MALE | 65          | -1                | -35              | WBC (10 <sup>3</sup> /uL)      | 4.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg<br>(56-70 years) | MALE | 65          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 3.87              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg<br>(56-70 years) | MALE | 65          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 4.47              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg<br>(56-70 years) | MALE | 65          | 29                | 31               | WBC (10 <sup>3</sup> /uL)      | 4.53              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg<br>(56-70 years) | MALE | 65          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 4.28              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR006  | 50 µg<br>(56-70 years) | MALE | 65          | 57                | 59               | WBC (10 <sup>3</sup> /uL)      | 5.58              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg<br>(56-70 years) | MALE | 64          | -1                | -35              | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 8                 | 7                | Alanine Aminotransferase (U/L)   | 26                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 29                | 31               | Alanine Aminotransferase (U/L)   | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 36                | 37               | Alanine Aminotransferase (U/L)   | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | -1                | -35              | Alkaline Phosphatase (U/L)       | 69                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 67                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 70                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 29                | 31               | Alkaline Phosphatase (U/L)       | 68                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 36                | 37               | Alkaline Phosphatase (U/L)       | 64                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | -1                | -35              | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 29                | 31               | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 36                | 37               | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | -1                | -35              | Creatinine (mg/dL)               | 0.94              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 1                 | 1                | Creatinine (mg/dL)               | 1.07              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 8                 | 7                | Creatinine (mg/dL)               | 1.06              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 29                | 31               | Creatinine (mg/dL)               | 1.09              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 36                | 37               | Creatinine (mg/dL)               | 1.02              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | -1                | -35              | Hemoglobin (g/dL)                | 15.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | -1                | -27              | Hemoglobin (g/dL)                | 15.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 1                 | 1                | Hemoglobin (g/dL)                | 15.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 8                 | 7                | Hemoglobin (g/dL)                | 15.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology            | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 29                | 31               | Hemoglobin (g/dL)               | 15.4 (Mild)       | NOT RELATED                 | Hemoglobin within institutional normal limits   | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 36                | 37               | Hemoglobin (g/dL)               | 15.2 (Mild)       | NOT RELATED                 | hemoglobin is within institutional normal range | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | -1                | -35              | PT (seconds)                    | 13.7              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | -1                | -35              | PTT (seconds)                   | 29.6              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | -1                | -35              | Platelets (10 <sup>3</sup> /uL) | 195               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | -1                | -27              | Platelets (10 <sup>3</sup> /uL) | 267               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 220               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 220               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 29                | 31               | Platelets (10 <sup>3</sup> /uL) | 208               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 227               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | -1                | -35              | Serum Lipase (U/L)              | 19.0              | N/A                         | N/A   | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 1                 | 1                | Serum Lipase (U/L)           | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 8                 | 7                | Serum Lipase (U/L)           | 16.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 29                | 31               | Serum Lipase (U/L)           | 17.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 36                | 37               | Serum Lipase (U/L)           | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | -1                | -35              | Total Bilirubin (mg/dL)      | 1.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 8                 | 7                | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 29                | 31               | Total Bilirubin (mg/dL)      | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 36                | 37               | Total Bilirubin (mg/dL)      | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | -1                | -35              | WBC (10 <sup>3</sup> /uL)    | 10.57             | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | -1                | -27              | WBC (10 <sup>3</sup> /uL)    | 6.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 5.29              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE | 64          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)    | 5.52              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR008  | 50 µg (56-70 years) | MALE   | 64          | 29                | 31               | WBC (10 <sup>3</sup> /uL)      | 4.64              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR008  | 50 µg (56-70 years) | MALE   | 64          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 5.61              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | -1                | -36              | Alanine Aminotransferase (U/L) | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 8                 | 7                | Alanine Aminotransferase (U/L) | 7                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 29                | 27               | Alanine Aminotransferase (U/L) | 7                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 36                | 35               | Alanine Aminotransferase (U/L) | 7                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | -1                | -36              | Alkaline Phosphatase (U/L)     | 62                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 65                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 8                 | 7                | Alkaline Phosphatase (U/L)     | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 29                | 27               | Alkaline Phosphatase (U/L)     | 62                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 36                | 35               | Alkaline Phosphatase (U/L)       | 58                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | -1                | -36              | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 29                | 27               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 36                | 35               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | -1                | -36              | Creatinine (mg/dL)               | 0.95              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Creatinine (mg/dL)               | 0.82              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 8                 | 7                | Creatinine (mg/dL)               | 0.83              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 29                | 27               | Creatinine (mg/dL)               | 0.91              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 36                | 35               | Creatinine (mg/dL)               | 0.87              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology            | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | -1                | -36              | Hemoglobin (g/dL)               | 12.9              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Hemoglobin (g/dL)               | 12.8              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 8                 | 7                | Hemoglobin (g/dL)               | 12.2 (Mild)       | NOT RELATED                 | hgb within INR                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 29                | 27               | Hemoglobin (g/dL)               | 12.3 (Mild)       | NOT RELATED                 | Hgb within institutional normal range           | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 36                | 35               | Hemoglobin (g/dL)               | 11.8 (Mild)       | NOT RELATED                 | Hemoglobin is within institutional normal range | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | -1                | -36              | PT (seconds)                    | 14.0              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | -1                | -36              | PTT (seconds)                   | 34.3              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | -1                | -36              | Platelets (10 <sup>3</sup> /uL) | 270               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 258               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 252               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 267               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 267               | N/A                         | N/A   | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | -1                | -36              | Serum Lipase (U/L)           | 19.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Serum Lipase (U/L)           | 18.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 8                 | 7                | Serum Lipase (U/L)           | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 29                | 27               | Serum Lipase (U/L)           | 12.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 36                | 35               | Serum Lipase (U/L)           | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | -1                | -36              | Total Bilirubin (mg/dL)      | 0.2               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 8                 | 7                | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 29                | 27               | Total Bilirubin (mg/dL)      | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 36                | 35               | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | -1                | -36              | WBC (10 <sup>3</sup> /uL)    | 6.37              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 4.38              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)    | 5.34              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 29                | 27               | WBC (10 <sup>3</sup> /uL)      | 5.61              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR009  | 50 µg (56-70 years) | FEMALE | 68          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 4.76              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE   | 66          | -1                | -34              | Alanine Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE   | 66          | 1                 | 1                | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE   | 66          | 8                 | 7                | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE   | 66          | 29                | 31               | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE   | 66          | 36                | 37               | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE   | 66          | -1                | -34              | Alkaline Phosphatase (U/L)     | 76                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE   | 66          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 67                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE   | 66          | 8                 | 7                | Alkaline Phosphatase (U/L)     | 65                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE   | 66          | 29                | 31               | Alkaline Phosphatase (U/L)     | 68                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 36                | 37               | Alkaline Phosphatase (U/L)       | 68                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | -1                | -34              | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 29                | 31               | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 36                | 37               | Aspartate Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | -1                | -34              | Creatinine (mg/dL)               | 0.87              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 1                 | 1                | Creatinine (mg/dL)               | 0.85              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 8                 | 7                | Creatinine (mg/dL)               | 0.94              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 29                | 31               | Creatinine (mg/dL)               | 0.84              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 36                | 37               | Creatinine (mg/dL)               | 0.92              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology            | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | -1                | -34              | Hemoglobin (g/dL)               | 15.6              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 1                 | 1                | Hemoglobin (g/dL)               | 15.1              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 8                 | 7                | Hemoglobin (g/dL)               | 14.5 (Mild)       | NOT RELATED                 | Hgb within institutional normal range           | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 29                | 31               | Hemoglobin (g/dL)               | 14.4 (Mild)       | NOT RELATED                 | hemoglobin within institutional normal range    | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 36                | 37               | Hemoglobin (g/dL)               | 14.2 (Mild)       | NOT RELATED                 | hemoglobin is within institutional normal range | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | -1                | -34              | PT (seconds)                    | 14.2              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | -1                | -34              | PTT (seconds)                   | 30.3              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | -1                | -34              | Platelets (10 <sup>3</sup> /uL) | 228               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 215               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 228               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 29                | 31               | Platelets (10 <sup>3</sup> /uL) | 224               | N/A                         | N/A   | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 256               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | -1                | -34              | Serum Lipase (U/L)              | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 1                 | 1                | Serum Lipase (U/L)              | 21.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 8                 | 7                | Serum Lipase (U/L)              | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 29                | 31               | Serum Lipase (U/L)              | 19.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 36                | 37               | Serum Lipase (U/L)              | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | -1                | -34              | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 8                 | 7                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 29                | 31               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 36                | 37               | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | -1                | -34              | WBC (10 <sup>3</sup> /uL)       | 6.26              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)       | 5.88              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 5.95              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 29                | 31               | WBC (10 <sup>3</sup> /uL)      | 6.34              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR011  | 50 µg (56-70 years) | MALE | 66          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 6.01              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years)   | MALE | 73          | -1                | -36              | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years)   | MALE | 73          | 1                 | 1                | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years)   | MALE | 73          | 8                 | 7                | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years)   | MALE | 73          | 29                | 27               | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years)   | MALE | 73          | 36                | 33               | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years)   | MALE | 73          | -1                | -36              | Alkaline Phosphatase (U/L)     | 42                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years)   | MALE | 73          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 48                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years)   | MALE | 73          | 8                 | 7                | Alkaline Phosphatase (U/L)     | 44                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 29                | 27               | Alkaline Phosphatase (U/L)       | 47                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 36                | 33               | Alkaline Phosphatase (U/L)       | 48                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | -1                | -36              | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 29                | 27               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 36                | 33               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | -1                | -36              | Creatinine (mg/dL)               | 0.92              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 1                 | 1                | Creatinine (mg/dL)               | 0.90              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 8                 | 7                | Creatinine (mg/dL)               | 1.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 29                | 27               | Creatinine (mg/dL)               | 0.93              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 36                | 33               | Creatinine (mg/dL)              | 0.98              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | -1                | -36              | Hemoglobin (g/dL)               | 14.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | -1                | -30              | Hemoglobin (g/dL)               | 14.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 1                 | 1                | Hemoglobin (g/dL)               | 15.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 8                 | 7                | Hemoglobin (g/dL)               | 14.8 (Mild)       | NOT RELATED                 | hgb within INR                       | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 29                | 27               | Hemoglobin (g/dL)               | 15.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 36                | 33               | Hemoglobin (g/dL)               | 15.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | -1                | -36              | PT (seconds)                    | 14.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | -1                | -36              | PTT (seconds)                   | 28.1              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | -1                | -36              | Platelets (10 <sup>3</sup> /uL) | 158               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | -1                | -30              | Platelets (10 <sup>3</sup> /uL) | 173               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 175               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 187               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 176               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 36                | 33               | Platelets (10 <sup>3</sup> /uL) | 193               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | -1                | -36              | Serum Lipase (U/L)              | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 1                 | 1                | Serum Lipase (U/L)              | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 8                 | 7                | Serum Lipase (U/L)              | 28.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 29                | 27               | Serum Lipase (U/L)              | 26.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 36                | 33               | Serum Lipase (U/L)              | 24.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | -1                | -36              | Total Bilirubin (mg/dL)         | 1.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 8                 | 7                | Total Bilirubin (mg/dL)         | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 29                | 27               | Total Bilirubin (mg/dL)         | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 36                | 33               | Total Bilirubin (mg/dL)         | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | -1                | -36              | WBC (10 <sup>3</sup> /uL)       | 5.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | -1                | -30              | WBC (10 <sup>3</sup> /uL)      | 5.21              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 4.91              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 5.09              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 29                | 27               | WBC (10 <sup>3</sup> /uL)      | 6.25              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR013  | 50 µg (≥71 years) | MALE | 73          | 36                | 33               | WBC (10 <sup>3</sup> /uL)      | 5.91              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | -1                | -35              | Alanine Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 1                 | 1                | Alanine Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 8                 | 7                | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 29                | 27               | Alanine Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 36                | 33               | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | -1                | -35              | Alkaline Phosphatase (U/L)     | 87                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 72                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 74                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 29                | 27               | Alkaline Phosphatase (U/L)       | 69                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 36                | 33               | Alkaline Phosphatase (U/L)       | 75                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | -1                | -35              | Aspartate Aminotransferase (U/L) | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 29                | 27               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 36                | 33               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | -1                | -35              | Creatinine (mg/dL)               | 1.07              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 1                 | 1                | Creatinine (mg/dL)               | 1.05              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 8                 | 7                | Creatinine (mg/dL)              | 1.00              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 29                | 27               | Creatinine (mg/dL)              | 1.05              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 36                | 33               | Creatinine (mg/dL)              | 1.13              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | -1                | -35              | Hemoglobin (g/dL)               | 14.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 1                 | 1                | Hemoglobin (g/dL)               | 13.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 8                 | 7                | Hemoglobin (g/dL)               | 13.5 (Mild)       | NOT RELATED                 | anemia due to blood draws            | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 29                | 27               | Hemoglobin (g/dL)               | 13.3 (Mild)       | NOT RELATED                 | anemia due to blood draws            | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 36                | 33               | Hemoglobin (g/dL)               | 13.3 (Mild)       | NOT RELATED                 | anemia due to blood draws            | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | -1                | -35              | PT (seconds)                    | 13.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | -1                | -35              | PTT (seconds)                   | 31.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | -1                | -35              | Platelets (10 <sup>3</sup> /uL) | 178               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 154               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 168               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 163               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 36                | 33               | Platelets (10 <sup>3</sup> /uL) | 163               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | -1                | -35              | Serum Lipase (U/L)              | 44.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 1                 | 1                | Serum Lipase (U/L)              | 43.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 8                 | 7                | Serum Lipase (U/L)              | 45.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 29                | 27               | Serum Lipase (U/L)              | 48.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 36                | 33               | Serum Lipase (U/L)              | 41.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | -1                | -35              | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 8                 | 7                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 29                | 27               | Total Bilirubin (mg/dL)         | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | 36                | 33               | Total Bilirubin (mg/dL)         | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years) | MALE | 74          | -1                | -35              | WBC (10 <sup>3</sup> /uL)       | 8.31              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR014  | 50 µg (≥71 years)   | MALE   | 74          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 6.43              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years)   | MALE   | 74          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 7.33              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years)   | MALE   | 74          | 29                | 27               | WBC (10 <sup>3</sup> /uL)      | 6.13              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR014  | 50 µg (≥71 years)   | MALE   | 74          | 36                | 33               | WBC (10 <sup>3</sup> /uL)      | 6.12              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | -1                | -34              | Alanine Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 1                 | 1                | Alanine Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 8                 | 7                | Alanine Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 29                | 27               | Alanine Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 36                | 35               | Alanine Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | -1                | -34              | Alkaline Phosphatase (U/L)     | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 63                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 60                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 29                | 27               | Alkaline Phosphatase (U/L)       | 65                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 36                | 35               | Alkaline Phosphatase (U/L)       | 59                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | -1                | -34              | Aspartate Aminotransferase (U/L) | 29                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 29                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 34                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 29                | 27               | Aspartate Aminotransferase (U/L) | 29                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 36                | 35               | Aspartate Aminotransferase (U/L) | 26                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | -1                | -34              | Creatinine (mg/dL)               | 0.95              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 1                 | 1                | Creatinine (mg/dL)               | 1.02              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 8                 | 7                | Creatinine (mg/dL)               | 0.99              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology         | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--|-------------------------------------|-------------------------------------|
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 29                | 27               | Creatinine (mg/dL)              | 1.07              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 36                | 35               | Creatinine (mg/dL)              | 0.91              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | -1                | -34              | Hemoglobin (g/dL)               | 11.5 (Mild)       | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | -1                | -22              | Hemoglobin (g/dL)               | 12.1              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 1                 | 1                | Hemoglobin (g/dL)               | 12.2              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 8                 | 7                | Hemoglobin (g/dL)               | 11.3 (Mild)       | NOT RELATED                 | within institutional normal range            | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 29                | 27               | Hemoglobin (g/dL)               | 12.2              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 36                | 35               | Hemoglobin (g/dL)               | 11.3 (Mild)       | NOT RELATED                 | hemoglobin within institutional normal range | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | -1                | -34              | PT (seconds)                    | 13.7              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | -1                | -34              | PTT (seconds)                   | 32.5              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | -1                | -34              | Platelets (10 <sup>3</sup> /uL) | 177               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | -1                | -22              | Platelets (10 <sup>3</sup> /uL) | 192               | N/A                         | N/A  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 181               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 190               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 189               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 199               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | -1                | -34              | Serum Lipase (U/L)              | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 1                 | 1                | Serum Lipase (U/L)              | 39.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 8                 | 7                | Serum Lipase (U/L)              | 31.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 29                | 27               | Serum Lipase (U/L)              | 39.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 36                | 35               | Serum Lipase (U/L)              | 39.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | -1                | -34              | Total Bilirubin (mg/dL)         | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 8                 | 7                | Total Bilirubin (mg/dL)         | 1.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg (56-70 years) | FEMALE | 60          | 29                | 27               | Total Bilirubin (mg/dL)         | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR016  | 50 µg<br>(56-70 years) | FEMALE | 60          | 36                | 35               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg<br>(56-70 years) | FEMALE | 60          | -1                | -34              | WBC (10 <sup>3</sup> /uL)      | 3.97              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg<br>(56-70 years) | FEMALE | 60          | -1                | -22              | WBC (10 <sup>3</sup> /uL)      | 4.40              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg<br>(56-70 years) | FEMALE | 60          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 4.16              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg<br>(56-70 years) | FEMALE | 60          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 4.02              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg<br>(56-70 years) | FEMALE | 60          | 29                | 27               | WBC (10 <sup>3</sup> /uL)      | 4.44              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR016  | 50 µg<br>(56-70 years) | FEMALE | 60          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 4.89              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg<br>(56-70 years) | FEMALE | 59          | -1                | -34              | Alanine Aminotransferase (U/L) | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg<br>(56-70 years) | FEMALE | 59          | 1                 | 1                | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg<br>(56-70 years) | FEMALE | 59          | 8                 | 7                | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg<br>(56-70 years) | FEMALE | 59          | 29                | 27               | Alanine Aminotransferase (U/L) | 11                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 36                | 35               | Alanine Aminotransferase (U/L)   | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | -1                | -34              | Alkaline Phosphatase (U/L)       | 57                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 56                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 29                | 27               | Alkaline Phosphatase (U/L)       | 54                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 36                | 35               | Alkaline Phosphatase (U/L)       | 64                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | -1                | -34              | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 29                | 27               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 36                | 35               | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology            | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | -1                | -34              | Creatinine (mg/dL)           | 0.90              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 1                 | 1                | Creatinine (mg/dL)           | 0.63              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 8                 | 7                | Creatinine (mg/dL)           | 0.63              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 29                | 27               | Creatinine (mg/dL)           | 0.69              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 36                | 35               | Creatinine (mg/dL)           | 0.73              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | -1                | -34              | Hemoglobin (g/dL)            | 12.5              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 1                 | 1                | Hemoglobin (g/dL)            | 12.6              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 8                 | 7                | Hemoglobin (g/dL)            | 11.7 (Mild)       | NOT RELATED                 | within institutional normal range               | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 29                | 27               | Hemoglobin (g/dL)            | 12.2 (Mild)       | NOT RELATED                 | hemoglobin within institutional range           | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 36                | 35               | Hemoglobin (g/dL)            | 12.0 (Mild)       | NOT RELATED                 | hemoglobin is within institutional normal range | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | -1                | -34              | PT (seconds)                 | 13.5              | N/A                         | N/A   | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | -1                | -34              | PTT (seconds)                   | 31.2              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | -1                | -34              | Platelets (10 <sup>3</sup> /uL) | 248               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 248               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 228               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 247               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 282               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | -1                | -34              | Serum Lipase (U/L)              | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 1                 | 1                | Serum Lipase (U/L)              | 20.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 8                 | 7                | Serum Lipase (U/L)              | 25.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 29                | 27               | Serum Lipase (U/L)              | 22.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 36                | 35               | Serum Lipase (U/L)              | 47.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | -1                | -34              | Total Bilirubin (mg/dL)         | 1.0               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 1                 | 1                | Total Bilirubin (mg/dL)         | 1.1               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 8                 | 7                | Total Bilirubin (mg/dL)        | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 29                | 27               | Total Bilirubin (mg/dL)        | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 36                | 35               | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | -1                | -34              | WBC (10 <sup>3</sup> /uL)      | 5.35              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 4.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 4.44              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 29                | 27               | WBC (10 <sup>3</sup> /uL)      | 4.94              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR017  | 50 µg (56-70 years) | FEMALE | 59          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 4.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years)   | MALE   | 83          | -1                | -35              | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years)   | MALE   | 83          | 1                 | 1                | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years)   | MALE   | 83          | 8                 | 7                | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 29                | 27               | Alanine Aminotransferase (U/L)   | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 36                | 33               | Alanine Aminotransferase (U/L)   | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | -1                | -35              | Alkaline Phosphatase (U/L)       | 112               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 110               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 100               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 29                | 27               | Alkaline Phosphatase (U/L)       | 98                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 36                | 33               | Alkaline Phosphatase (U/L)       | 99                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | -1                | -35              | Aspartate Aminotransferase (U/L) | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 23                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 29                | 27               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology         | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--|-------------------------------------|-------------------------------------|
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 36                | 33               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | -1                | -35              | Creatinine (mg/dL)               | 0.82              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 1                 | 1                | Creatinine (mg/dL)               | 0.78              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 8                 | 7                | Creatinine (mg/dL)               | 0.71              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 29                | 27               | Creatinine (mg/dL)               | 0.80              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 36                | 33               | Creatinine (mg/dL)               | 0.76              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | -1                | -35              | Hemoglobin (g/dL)                | 15.2              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 1                 | 1                | Hemoglobin (g/dL)                | 16.4              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 8                 | 7                | Hemoglobin (g/dL)                | 15.1 (Mild)       | NOT RELATED                 | Hgb within institutional normal range        | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 29                | 27               | Hemoglobin (g/dL)                | 15.3 (Mild)       | NOT RELATED                 | hemoglobin within institutional normal range | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 36                | 33               | Hemoglobin (g/dL)                | 15.4 (Mild)       | NOT RELATED                 | Hemoglobin within institutional normal range | NC- DOSE NOT CHANGED                | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | -1                | -35              | PT (seconds)                    | 14.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | -1                | -35              | PTT (seconds)                   | 30.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | -1                | -35              | Platelets (10 <sup>3</sup> /uL) | 167               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 182               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 182               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 173               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 36                | 33               | Platelets (10 <sup>3</sup> /uL) | 183               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | -1                | -35              | Serum Lipase (U/L)              | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 1                 | 1                | Serum Lipase (U/L)              | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 8                 | 7                | Serum Lipase (U/L)              | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 29                | 27               | Serum Lipase (U/L)              | 31.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 36                | 33               | Serum Lipase (U/L)              | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | -1                | -35              | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 8                 | 7                | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 29                | 27               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 36                | 33               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | -1                | -35              | WBC (10 <sup>3</sup> /uL)      | 6.47              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 6.47              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 5.53              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 29                | 27               | WBC (10 <sup>3</sup> /uL)      | 6.69              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR018  | 50 µg (≥71 years) | MALE | 83          | 36                | 33               | WBC (10 <sup>3</sup> /uL)      | 6.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | -1                | -32              | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 1                 | 1                | Alanine Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 8                 | 7                | Alanine Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 29                | 27               | Alanine Aminotransferase (U/L)   | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 36                | 35               | Alanine Aminotransferase (U/L)   | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | -1                | -32              | Alkaline Phosphatase (U/L)       | 71                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 73                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 65                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 29                | 27               | Alkaline Phosphatase (U/L)       | 69                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 36                | 35               | Alkaline Phosphatase (U/L)       | 69                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | -1                | -32              | Aspartate Aminotransferase (U/L) | 21                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 29                | 27               | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology         | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--|-------------------------------------|-------------------------------------|
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 36                | 35               | Aspartate Aminotransferase (U/L) | 26                | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | -1                | -32              | Creatinine (mg/dL)               | 0.92              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 1                 | 1                | Creatinine (mg/dL)               | 1.01              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 8                 | 7                | Creatinine (mg/dL)               | 0.94              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 29                | 27               | Creatinine (mg/dL)               | 0.97              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 36                | 35               | Creatinine (mg/dL)               | 0.90              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | -1                | -32              | Hemoglobin (g/dL)                | 15.0              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 1                 | 1                | Hemoglobin (g/dL)                | 14.8              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 8                 | 7                | Hemoglobin (g/dL)                | 12.9 (Mild)       | NOT RELATED                 | anemia due to blood draws                    | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 29                | 27               | Hemoglobin (g/dL)                | 13.8 (Mild)       | NOT RELATED                 | hemoglobin within institutional normal range | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 36                | 35               | Hemoglobin (g/dL)                | 13.5 (Mild)       | NOT RELATED                 | anemia due to blood draws                    | NC- DOSE NOT CHANGED                | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology  | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 57                | 55               | Hemoglobin (g/dL)               | 14.7 (Mild)       | NOT RELATED                 | Hgb within institutional normal range | NA- NOT APPLICABLE                  | No                                  |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | -1                | -32              | PT (seconds)                    | 12.7              | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | -1                | -32              | PTT (seconds)                   | 28.4              | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | -1                | -32              | Platelets (10 <sup>3</sup> /uL) | 220               | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 256               | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 211               | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 268               | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 241               | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 57                | 55               | Platelets (10 <sup>3</sup> /uL) | 295               | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | -1                | -32              | Serum Lipase (U/L)              | 58.0              | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 1                 | 1                | Serum Lipase (U/L)              | 57.0              | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 8                 | 7                | Serum Lipase (U/L)              | 62.0              | N/A                         | N/A                                   | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years) | MALE | 73          | 29                | 27               | Serum Lipase (U/L)              | 39.0              | N/A                         | N/A                                   | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR021  | 50 µg (≥71 years)   | MALE | 73          | 36                | 35               | Serum Lipase (U/L)             | 62.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years)   | MALE | 73          | -1                | -32              | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years)   | MALE | 73          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years)   | MALE | 73          | 8                 | 7                | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years)   | MALE | 73          | 29                | 27               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years)   | MALE | 73          | 36                | 35               | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years)   | MALE | 73          | -1                | -32              | WBC (10 <sup>3</sup> /uL)      | 6.77              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years)   | MALE | 73          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 6.04              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years)   | MALE | 73          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 6.12              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years)   | MALE | 73          | 29                | 27               | WBC (10 <sup>3</sup> /uL)      | 6.47              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years)   | MALE | 73          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 7.53              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR021  | 50 µg (≥71 years)   | MALE | 73          | 57                | 55               | WBC (10 <sup>3</sup> /uL)      | 8.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | -1                | -28              | Alanine Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 8                 | 7                | Alanine Aminotransferase (U/L)   | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 29                | 31               | Alanine Aminotransferase (U/L)   | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 36                | 37               | Alanine Aminotransferase (U/L)   | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | -1                | -28              | Alkaline Phosphatase (U/L)       | 67                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 65                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 68                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 29                | 31               | Alkaline Phosphatase (U/L)       | 63                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 36                | 37               | Alkaline Phosphatase (U/L)       | 73                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | -1                | -28              | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 29                | 31               | Aspartate Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 36                | 37               | Aspartate Aminotransferase (U/L) | 14                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | -1                | -28              | Creatinine (mg/dL)               | 0.76              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 1                 | 1                | Creatinine (mg/dL)               | 0.78              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 8                 | 7                | Creatinine (mg/dL)               | 0.84              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 29                | 31               | Creatinine (mg/dL)               | 0.85              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 36                | 37               | Creatinine (mg/dL)               | 0.88              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | -1                | -28              | Hemoglobin (g/dL)                | 16.9              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 1                 | 1                | Hemoglobin (g/dL)                | 16.3              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 8                 | 7                | Hemoglobin (g/dL)                | 15.6 (Mild)       | NOT RELATED                 | hgb within INR                       | NC- DOSE NOT CHANGED                | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex  | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology         | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--|-------------------------------------|-------------------------------------|
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 29                | 31               | Hemoglobin (g/dL)               | 16.0 (Mild)       | NOT RELATED                 | hemoglobin within institutional normal range | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 36                | 37               | Hemoglobin (g/dL)               | 16.3              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | -1                | -28              | PT (seconds)                    | 13.1              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | -1                | -28              | PTT (seconds)                   | 31.9              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | -1                | -28              | Platelets (10 <sup>3</sup> /uL) | 264               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 262               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 249               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 29                | 31               | Platelets (10 <sup>3</sup> /uL) | 224               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 36                | 37               | Platelets (10 <sup>3</sup> /uL) | 260               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | -1                | -28              | Serum Lipase (U/L)              | 46.0              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 1                 | 1                | Serum Lipase (U/L)              | 35.0              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg (56-70 years) | MALE | 60          | 8                 | 7                | Serum Lipase (U/L)              | 39.0              | N/A                         | N/A  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR024  | 50 µg<br>(56-70 years) | MALE   | 60          | 29                | 31               | Serum Lipase (U/L)             | 43.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg<br>(56-70 years) | MALE   | 60          | 36                | 37               | Serum Lipase (U/L)             | 37.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg<br>(56-70 years) | MALE   | 60          | -1                | -28              | Total Bilirubin (mg/dL)        | 0.7               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg<br>(56-70 years) | MALE   | 60          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg<br>(56-70 years) | MALE   | 60          | 8                 | 7                | Total Bilirubin (mg/dL)        | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg<br>(56-70 years) | MALE   | 60          | 29                | 31               | Total Bilirubin (mg/dL)        | 0.8               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg<br>(56-70 years) | MALE   | 60          | 36                | 37               | Total Bilirubin (mg/dL)        | 0.9               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg<br>(56-70 years) | MALE   | 60          | -1                | -28              | WBC (10 <sup>3</sup> /uL)      | 7.27              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg<br>(56-70 years) | MALE   | 60          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 11.98<br>(Mild)   | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg<br>(56-70 years) | MALE   | 60          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 9.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg<br>(56-70 years) | MALE   | 60          | 29                | 31               | WBC (10 <sup>3</sup> /uL)      | 6.82              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR024  | 50 µg<br>(56-70 years) | MALE   | 60          | 36                | 37               | WBC (10 <sup>3</sup> /uL)      | 8.15              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg<br>(56-70 years) | FEMALE | 61          | -1                | -29              | Alanine Aminotransferase (U/L) | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 8                 | 7                | Alanine Aminotransferase (U/L)   | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 29                | 27               | Alanine Aminotransferase (U/L)   | 10                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 36                | 33               | Alanine Aminotransferase (U/L)   | 9                 | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | -1                | -29              | Alkaline Phosphatase (U/L)       | 81                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 90                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 75                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 29                | 27               | Alkaline Phosphatase (U/L)       | 80                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 36                | 33               | Alkaline Phosphatase (U/L)       | 81                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | -1                | -29              | Aspartate Aminotransferase (U/L) | 25                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 27                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 29                | 27               | Aspartate Aminotransferase (U/L) | 26                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 36                | 33               | Aspartate Aminotransferase (U/L) | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | -1                | -29              | Creatinine (mg/dL)               | 0.67              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 1                 | 1                | Creatinine (mg/dL)               | 0.73              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 8                 | 7                | Creatinine (mg/dL)               | 0.79              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 29                | 27               | Creatinine (mg/dL)               | 0.81              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 36                | 33               | Creatinine (mg/dL)               | 0.77              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | -1                | -29              | Hemoglobin (g/dL)                | 15.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 1                 | 1                | Hemoglobin (g/dL)                | 14.8              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 8                 | 7                | Hemoglobin (g/dL)                | 14.4 (Mild)       | NOT RELATED                 | hgb within INR                       | NC- DOSE NOT CHANGED                | No                                  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group   | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology         | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|---------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--|-------------------------------------|-------------------------------------|
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 29                | 27               | Hemoglobin (g/dL)               | 14.5 (Mild)       | NOT RELATED                 | Hgb within institutional normal range        | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 36                | 33               | Hemoglobin (g/dL)               | 14.4 (Mild)       | NOT RELATED                 | hemoglobin within institutional normal range | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | -1                | -29              | PT (seconds)                    | 14.0              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | -1                | -29              | PTT (seconds)                   | 31.6              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | -1                | -29              | Platelets (10 <sup>3</sup> /uL) | 188               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 184               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 205               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 170               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 36                | 33               | Platelets (10 <sup>3</sup> /uL) | 194               | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | -1                | -29              | Serum Lipase (U/L)              | 45.0              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 1                 | 1                | Serum Lipase (U/L)              | 43.0              | N/A                         | N/A  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg (56-70 years) | FEMALE | 61          | 8                 | 7                | Serum Lipase (U/L)              | 52.0              | N/A                         | N/A  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group      | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|------------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR028  | 50 µg<br>(56-70 years) | FEMALE | 61          | 29                | 27               | Serum Lipase (U/L)             | 48.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg<br>(56-70 years) | FEMALE | 61          | 36                | 33               | Serum Lipase (U/L)             | 44.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg<br>(56-70 years) | FEMALE | 61          | -1                | -29              | Total Bilirubin (mg/dL)        | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg<br>(56-70 years) | FEMALE | 61          | 1                 | 1                | Total Bilirubin (mg/dL)        | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg<br>(56-70 years) | FEMALE | 61          | 8                 | 7                | Total Bilirubin (mg/dL)        | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg<br>(56-70 years) | FEMALE | 61          | 29                | 27               | Total Bilirubin (mg/dL)        | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg<br>(56-70 years) | FEMALE | 61          | 36                | 33               | Total Bilirubin (mg/dL)        | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg<br>(56-70 years) | FEMALE | 61          | -1                | -29              | WBC (10 <sup>3</sup> /uL)      | 5.68              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg<br>(56-70 years) | FEMALE | 61          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)      | 7.56              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg<br>(56-70 years) | FEMALE | 61          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)      | 5.56              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg<br>(56-70 years) | FEMALE | 61          | 29                | 27               | WBC (10 <sup>3</sup> /uL)      | 5.54              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR028  | 50 µg<br>(56-70 years) | FEMALE | 61          | 36                | 33               | WBC (10 <sup>3</sup> /uL)      | 6.64              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg<br>(≥71 years)   | FEMALE | 78          | -1                | -28              | Alanine Aminotransferase (U/L) | 30                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)               | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|--|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 1                 | 1                | Alanine Aminotransferase (U/L)             | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 8                 | 7                | Alanine Aminotransferase (U/L)             | 28                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 29                | 27               | Alanine Aminotransferase (U/L)             | 24                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 36                | 35               | Alanine Aminotransferase (U/L)             | 22                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | -1                | -28              | Alkaline Phosphatase (10 <sup>3</sup> /uL) | 102               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 1                 | 1                | Alkaline Phosphatase (U/L)                 | 88                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 8                 | 7                | Alkaline Phosphatase (U/L)                 | 95                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 29                | 27               | Alkaline Phosphatase (U/L)                 | 89                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 36                | 35               | Alkaline Phosphatase (U/L)                 | 84                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | -1                | -28              | Aspartate Aminotransferase (U/L)           | 20                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 29                | 27               | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 36                | 35               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | -1                | -28              | Creatinine (mg/dL)               | 0.66              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 1                 | 1                | Creatinine (mg/dL)               | 0.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 8                 | 7                | Creatinine (mg/dL)               | 0.65              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 29                | 27               | Creatinine (mg/dL)               | 0.67              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 36                | 35               | Creatinine (mg/dL)               | 0.69              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | -1                | -28              | Hemoglobin (g/dL)                | 14.7              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 1                 | 1                | Hemoglobin (g/dL)                | 13.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology            | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 8                 | 7                | Hemoglobin (g/dL)               | 13.4 (Mild)       | NOT RELATED                 | hgb within INR                                  | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 29                | 27               | Hemoglobin (g/dL)               | 13.1 (Mild)       | NOT RELATED                 | Hgb within institutional normal range           | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 36                | 35               | Hemoglobin (g/dL)               | 12.8 (Mild)       | NOT RELATED                 | Hemoglobin is within institutional normal range | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | -1                | -28              | PT (seconds)                    | 13.9              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | -1                | -28              | PTT (seconds)                   | 33.3              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | -1                | -28              | Platelets (10 <sup>3</sup> /uL) | 355               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 321               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 350               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 327               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 342               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | -1                | -28              | Serum Lipase (U/L)              | 28.0              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 1                 | 1                | Serum Lipase (U/L)              | 28.0              | N/A                         | N/A   | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 8                 | 7                | Serum Lipase (U/L)           | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 29                | 27               | Serum Lipase (U/L)           | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 36                | 35               | Serum Lipase (U/L)           | 29.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | -1                | -28              | Total Bilirubin (mg/dL)      | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 8                 | 7                | Total Bilirubin (mg/dL)      | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 29                | 27               | Total Bilirubin (mg/dL)      | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 36                | 35               | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | -1                | -28              | WBC (10 <sup>3</sup> /uL)    | 7.43              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 7.14              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)    | 5.82              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 29                | 27               | WBC (10 <sup>3</sup> /uL)    | 6.53              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR030  | 50 µg (≥71 years) | FEMALE | 78          | 36                | 35               | WBC (10 <sup>3</sup> /uL)    | 5.08              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | -1                | -24              | Alanine Aminotransferase (U/L)   | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 1                 | 1                | Alanine Aminotransferase (U/L)   | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 8                 | 7                | Alanine Aminotransferase (U/L)   | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 29                | 27               | Alanine Aminotransferase (U/L)   | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 36                | 35               | Alanine Aminotransferase (U/L)   | 12                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | -1                | -24              | Alkaline Phosphatase (U/L)       | 55                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 1                 | 1                | Alkaline Phosphatase (U/L)       | 60                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 8                 | 7                | Alkaline Phosphatase (U/L)       | 58                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 29                | 27               | Alkaline Phosphatase (U/L)       | 56                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 36                | 35               | Alkaline Phosphatase (U/L)       | 53                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | -1                | -24              | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 29                | 27               | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 36                | 35               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | -1                | -24              | Creatinine (mg/dL)               | 0.89              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 1                 | 1                | Creatinine (mg/dL)               | 0.88              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 8                 | 7                | Creatinine (mg/dL)               | 0.94              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 29                | 27               | Creatinine (mg/dL)               | 0.98              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 36                | 35               | Creatinine (mg/dL)               | 0.92              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | -1                | -24              | Hemoglobin (g/dL)                | 14.5              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 1                 | 1                | Hemoglobin (g/dL)                | 14.6              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology            | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 8                 | 7                | Hemoglobin (g/dL)               | 13.7 (Mild)       | NOT RELATED                 | Hgb within institutional normal range           | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 29                | 27               | Hemoglobin (g/dL)               | 13.5 (Mild)       | NOT RELATED                 | Hemoglobin within institutional normal limits   | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 36                | 35               | Hemoglobin (g/dL)               | 13.8 (Mild)       | NOT RELATED                 | hemoglobin is within institutional normal range | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | -1                | -24              | PT (seconds)                    | 13.7              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | -1                | -24              | PTT (seconds)                   | 31.2              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | -1                | -24              | Platelets (10 <sup>3</sup> /uL) | 199               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 215               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 196               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 192               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 207               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | -1                | -24              | Serum Lipase (U/L)              | 50.0              | N/A                         | N/A   | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 1                 | 1                | Serum Lipase (U/L)           | 181.0 (Severe)    | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 8                 | 7                | Serum Lipase (U/L)           | 336.0 (Severe)    | NOT RELATED                 | Baseline lipase elevated             | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 15                | 13               | Serum Lipase (U/L)           | 50.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 29                | 27               | Serum Lipase (U/L)           | 48.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 36                | 35               | Serum Lipase (U/L)           | 54.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | -1                | -24              | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 1                 | 1                | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 8                 | 7                | Total Bilirubin (mg/dL)      | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 29                | 27               | Total Bilirubin (mg/dL)      | 0.6               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 36                | 35               | Total Bilirubin (mg/dL)      | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | -1                | -24              | WBC (10 <sup>3</sup> /uL)    | 5.75              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)    | 5.35              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)    | 5.54              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)   | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|--------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 29                | 27               | WBC (10 <sup>3</sup> /uL)      | 5.13              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR035  | 50 µg (≥71 years) | FEMALE | 77          | 36                | 35               | WBC (10 <sup>3</sup> /uL)      | 5.30              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | -1                | -24              | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 1                 | 1                | Alanine Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 8                 | 7                | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 29                | 27               | Alanine Aminotransferase (U/L) | 15                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 36                | 35               | Alanine Aminotransferase (U/L) | 13                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | -1                | -24              | Alkaline Phosphatase (U/L)     | 74                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 1                 | 1                | Alkaline Phosphatase (U/L)     | 68                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 8                 | 7                | Alkaline Phosphatase (U/L)     | 62                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 29                | 27               | Alkaline Phosphatase (U/L)     | 69                | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)     | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|----------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 36                | 35               | Alkaline Phosphatase (U/L)       | 66                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | -1                | -24              | Aspartate Aminotransferase (U/L) | 18                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 1                 | 1                | Aspartate Aminotransferase (U/L) | 19                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 8                 | 7                | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 29                | 27               | Aspartate Aminotransferase (U/L) | 17                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 36                | 35               | Aspartate Aminotransferase (U/L) | 16                | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | -1                | -24              | Creatinine (mg/dL)               | 0.73              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 1                 | 1                | Creatinine (mg/dL)               | 0.78              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 8                 | 7                | Creatinine (mg/dL)               | 0.85              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 29                | 27               | Creatinine (mg/dL)               | 0.77              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 36                | 35               | Creatinine (mg/dL)               | 0.74              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology            | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|---|-------------------------------------|-------------------------------------|
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | -1                | -24              | Hemoglobin (g/dL)               | 15.6              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 1                 | 1                | Hemoglobin (g/dL)               | 15.4              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 8                 | 7                | Hemoglobin (g/dL)               | 14.6 (Mild)       | NOT RELATED                 | Hgb within institutional normal range           | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 29                | 27               | Hemoglobin (g/dL)               | 14.5 (Mild)       | NOT RELATED                 | hemoglobin within institutional normal range    | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 36                | 35               | Hemoglobin (g/dL)               | 14.1 (Mild)       | NOT RELATED                 | hemoglobin is within institutional normal range | NC- DOSE NOT CHANGED                | No                                  |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | -1                | -24              | PT (seconds)                    | 12.8              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | -1                | -24              | PTT (seconds)                   | 31.0              | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | -1                | -24              | Platelets (10 <sup>3</sup> /uL) | 272               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 1                 | 1                | Platelets (10 <sup>3</sup> /uL) | 246               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 8                 | 7                | Platelets (10 <sup>3</sup> /uL) | 235               | N/A                         | N/A   | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 29                | 27               | Platelets (10 <sup>3</sup> /uL) | 318               | N/A                         | N/A   | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units)    | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|---------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 36                | 35               | Platelets (10 <sup>3</sup> /uL) | 260               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | -1                | -24              | Serum Lipase (U/L)              | 27.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 1                 | 1                | Serum Lipase (U/L)              | 32.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 8                 | 7                | Serum Lipase (U/L)              | 33.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 29                | 27               | Serum Lipase (U/L)              | 48.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 36                | 35               | Serum Lipase (U/L)              | 34.0              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | -1                | -24              | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 1                 | 1                | Total Bilirubin (mg/dL)         | 0.5               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 8                 | 7                | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 29                | 27               | Total Bilirubin (mg/dL)         | 0.3               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 36                | 35               | Total Bilirubin (mg/dL)         | 0.4               | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | -1                | -24              | WBC (10 <sup>3</sup> /uL)       | 8.07              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 1                 | 1                | WBC (10 <sup>3</sup> /uL)       | 6.50              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix E (continued)**  
**Listing of Abnormal Clinical Laboratory Results**

| Subject ID | Vaccination Group | Sex    | Age (years) | Planned Study Day | Actual Study Day | Laboratory Parameter (Units) | Result (Severity) | Relationship to Vaccination | If Not Related, Alternative Etiology | Action Taken with Study Vaccination | Subject Discontinued Due to Result? |
|------------|-------------------|--------|-------------|-------------------|------------------|------------------------------|-------------------|-----------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 8                 | 7                | WBC (10 <sup>3</sup> /uL)    | 6.80              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 29                | 27               | WBC (10 <sup>3</sup> /uL)    | 7.77              | N/A                         | N/A                                  | N/A                                 | N/A                                 |
| CV01VR037  | 50 µg (≥71 years) | FEMALE | 74          | 36                | 35               | WBC (10 <sup>3</sup> /uL)    | 5.60              | N/A                         | N/A                                  | N/A                                 | N/A                                 |

### APPENDIX F: Vital Signs Listing

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01EM003  | 250 µg<br>(18-55 years) | -1                | -21              | 37.2             | 121                            | 85                              | 80                     | 79.9        | 184.5       |
| CV01EM003  | 250 µg<br>(18-55 years) | 1                 | 1                | 36.6             | 114                            | 66                              | 81                     | .           | .           |
| CV01EM003  | 250 µg<br>(18-55 years) | 8                 | 8                | 36.4             | 108                            | 73                              | 76                     | .           | .           |
| CV01EM003  | 250 µg<br>(18-55 years) | 15                | 15               | 36.2             | 120                            | 82                              | 82                     | .           | .           |
| CV01EM003  | 250 µg<br>(18-55 years) | 29                | 29               | 36.3             | 123                            | 76                              | 82                     | .           | .           |
| CV01EM003  | 250 µg<br>(18-55 years) | 36                | 36               | 36.1             | 114                            | 77                              | 71                     | .           | .           |
| CV01EM003  | 250 µg<br>(18-55 years) | 43                | 43               | 36.5             | 120                            | 74                              | 73                     | .           | .           |
| CV01EM003  | 250 µg<br>(18-55 years) | 57                | 57               | 36.6             | 111                            | 78                              | 68                     | .           | .           |
| CV01EM003  | 250 µg<br>(18-55 years) | 119               | 116              | 36.6             | 119                            | 79                              | 75                     | .           | .           |
| CV01EM004  | 100 µg<br>(18-55 years) | -1                | -3               | 37.3             | 115                            | 80                              | 64                     | 84.4        | 175.5       |
| CV01EM004  | 100 µg<br>(18-55 years) | 1                 | 1                | 36.6             | 110                            | 76                              | 64                     | .           | .           |
| CV01EM004  | 100 µg<br>(18-55 years) | 8                 | 7                | 36.4             | 130                            | 82                              | 79                     | .           | .           |
| CV01EM004  | 100 µg<br>(18-55 years) | 15                | 14               | 37.1             | 130                            | 82                              | 102 (Mild)             | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01EM004  | 100 µg<br>(18-55 years) | 29                | 28               | 36.4             | 128                            | 80                              | 73                     | .           | .           |
| CV01EM004  | 100 µg<br>(18-55 years) | 36                | 35               | 36.6             | 119                            | 82                              | 75                     | .           | .           |
| CV01EM004  | 100 µg<br>(18-55 years) | 43                | 42               | 36.3             | 121                            | 79                              | 80                     | .           | .           |
| CV01EM004  | 100 µg<br>(18-55 years) | 57                | 55               | 37.1             | 126                            | 83                              | 63                     | .           | .           |
| CV01EM004  | 100 µg<br>(18-55 years) | 119               | 113              | 36.6             | 125                            | 80                              | 66                     | .           | .           |
| CV01EM005  | 100 µg<br>(18-55 years) | -1                | -3               | 37.1             | 137                            | 98 (Moderate)                   | 78                     | 68.8        | 169.4       |
| CV01EM005  | 100 µg<br>(18-55 years) | 1                 | 1                | 36.4             | 138                            | 90                              | 73                     | .           | .           |
| CV01EM005  | 100 µg<br>(18-55 years) | 8                 | 8                | 37.2             | 138                            | 80                              | 78                     | .           | .           |
| CV01EM005  | 100 µg<br>(18-55 years) | 15                | 15               | 37.1             | 137                            | 90                              | 67                     | .           | .           |
| CV01EM005  | 100 µg<br>(18-55 years) | 29                | 28               | 36.9             | 133                            | 87                              | 92                     | .           | .           |
| CV01EM005  | 100 µg<br>(18-55 years) | 36                | 35               | 37.2             | 136                            | 89                              | 82                     | .           | .           |
| CV01EM005  | 100 µg<br>(18-55 years) | 43                | 42               | 37.1             | 133                            | 84                              | 78                     | .           | .           |
| CV01EM005  | 100 µg<br>(18-55 years) | 57                | 56               | 37.1             | 129                            | 84                              | 86                     | .           | .           |
| CV01EM005  | 100 µg<br>(18-55 years) | 119               | 113              | 36.1             | 121                            | 89                              | 89                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01EM007  | 100 µg<br>(18-55 years) | -1                | -3               | 36.8             | 130                            | 83                              | 63                     | 93          | 181.7       |
| CV01EM007  | 100 µg<br>(18-55 years) | 1                 | 1                | 37               | 128                            | 81                              | 76                     | .           | .           |
| CV01EM007  | 100 µg<br>(18-55 years) | 8                 | 7                | 36.8             | 117                            | 75                              | 68                     | .           | .           |
| CV01EM007  | 100 µg<br>(18-55 years) | 15                | 13               | 37.2             | 117                            | 81                              | 73                     | .           | .           |
| CV01EM007  | 100 µg<br>(18-55 years) | 29                | 28               | 36.4             | 134                            | 89                              | 68                     | .           | .           |
| CV01EM007  | 100 µg<br>(18-55 years) | 36                | 34               | 36.4             | 109                            | 71                              | 62                     | .           | .           |
| CV01EM007  | 100 µg<br>(18-55 years) | 43                | 40               | 36.9             | 100                            | 66                              | 78                     | .           | .           |
| CV01EM007  | 100 µg<br>(18-55 years) | 57                | 55               | 36.3             | 111                            | 75                              | 76                     | .           | .           |
| CV01EM007  | 100 µg<br>(18-55 years) | 119               | 120              | 37               | 110                            | 69                              | 60                     | .           | .           |
| CV01EM009  | 100 µg<br>(18-55 years) | -1                | -3               | 36.7             | 106                            | 68                              | 51 (Mild)              | 73.5        | 172         |
| CV01EM009  | 100 µg<br>(18-55 years) | 1                 | 1                | 36.7             | 129                            | 74                              | 55                     | .           | .           |
| CV01EM009  | 100 µg<br>(18-55 years) | 8                 | 8                | 36.9             | 122                            | 72                              | 85                     | .           | .           |
| CV01EM009  | 100 µg<br>(18-55 years) | 15                | 15               | 37.1             | 120                            | 74                              | 55                     | .           | .           |
| CV01EM009  | 100 µg<br>(18-55 years) | 29                | 29               | 37.1             | 118                            | 78                              | 58                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01EM009  | 100 µg<br>(18-55 years) | 36                | 36               | 36.8             | 117                            | 69                              | 82                     | .           | .           |
| CV01EM009  | 100 µg<br>(18-55 years) | 43                | 43               | 36.6             | 108                            | 76                              | 53 (Mild)              | .           | .           |
| CV01EM009  | 100 µg<br>(18-55 years) | 57                | 55               | 36.2             | 113                            | 70                              | 57                     | .           | .           |
| CV01EM009  | 100 µg<br>(18-55 years) | 119               | 120              | 36.9             | 123                            | 74                              | 65                     | .           | .           |
| CV01EM010  | 100 µg<br>(18-55 years) | -1                | -3               | 37.3             | 116                            | 77                              | 53 (Mild)              | 69.7        | 160.7       |
| CV01EM010  | 100 µg<br>(18-55 years) | 1                 | 1                | 36.6             | 114                            | 78                              | 53 (Mild)              | .           | .           |
| CV01EM010  | 100 µg<br>(18-55 years) | 8                 | 8                | 37.1             | 101                            | 67                              | 56                     | .           | .           |
| CV01EM010  | 100 µg<br>(18-55 years) | 15                | 13               | 37.1             | 109                            | 67                              | 91                     | .           | .           |
| CV01EM010  | 100 µg<br>(18-55 years) | 29                | 29               | 37.3             | 106                            | 76                              | 83                     | .           | .           |
| CV01EM010  | 100 µg<br>(18-55 years) | 36                | 35               | 37.6             | 107                            | 66                              | 80                     | .           | .           |
| CV01EM010  | 100 µg<br>(18-55 years) | 43                | 42               | 36.9             | 110                            | 74                              | 96                     | .           | .           |
| CV01EM010  | 100 µg<br>(18-55 years) | 57                | 56               | 36.9             | 108                            | 74                              | 66                     | .           | .           |
| CV01EM010  | 100 µg<br>(18-55 years) | 119               | 113              | 37.4             | 121                            | 80                              | 68                     | .           | .           |
| CV01EM012  | 100 µg<br>(18-55 years) | -1                | -3               | 36.9             | 137                            | 81                              | 63                     | 76.1        | 170         |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01EM012  | 100 µg<br>(18-55 years) | 1                 | 1                | 36.6             | 111                            | 71                              | 63                     | .           | .           |
| CV01EM012  | 100 µg<br>(18-55 years) | 8                 | 8                | 36.8             | 105                            | 65                              | 59                     | .           | .           |
| CV01EM012  | 100 µg<br>(18-55 years) | 15                | 15               | 36.7             | 111                            | 73                              | 63                     | .           | .           |
| CV01EM012  | 100 µg<br>(18-55 years) | 29                | 29               | 36.6             | 118                            | 69                              | 73                     | .           | .           |
| CV01EM012  | 100 µg<br>(18-55 years) | 36                | 36               | 37               | 119                            | 66                              | 64                     | .           | .           |
| CV01EM012  | 100 µg<br>(18-55 years) | 43                | 43               | 37.1             | 123                            | 77                              | 74                     | .           | .           |
| CV01EM012  | 100 µg<br>(18-55 years) | 57                | 57               | 36.3             | 114                            | 69                              | 76                     | .           | .           |
| CV01EM012  | 100 µg<br>(18-55 years) | 119               | 113              | 36.6             | 112                            | 68                              | 66                     | .           | .           |
| CV01EM016  | 250 µg<br>(18-55 years) | -1                | -20              | 37.3             | 115                            | 73                              | 76                     | 55.7        | 157.5       |
| CV01EM016  | 250 µg<br>(18-55 years) | 1                 | 1                | 37.2             | 120                            | 78                              | 66                     | .           | .           |
| CV01EM016  | 250 µg<br>(18-55 years) | 8                 | 7                | 37.3             | 107                            | 74                              | 74                     | .           | .           |
| CV01EM016  | 250 µg<br>(18-55 years) | 15                | 16               | 37.4             | 111                            | 76                              | 75                     | .           | .           |
| CV01EM016  | 250 µg<br>(18-55 years) | 29                | 28               | 36.8             | 104                            | 77                              | 75                     | .           | .           |
| CV01EM016  | 250 µg<br>(18-55 years) | 36                | 35               | 37               | 105                            | 71                              | 79                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01EM016  | 250 µg<br>(18-55 years) | 43                | 43               | 37.2             | 115                            | 77                              | 78                     | .           | .           |
| CV01EM016  | 250 µg<br>(18-55 years) | 57                | 56               | 37.3             | 121                            | 83                              | 86                     | .           | .           |
| CV01EM016  | 250 µg<br>(18-55 years) | 119               | 116              | 37.1             | 121                            | 79                              | 79                     | .           | .           |
| CV01EM020  | 250 µg<br>(18-55 years) | -1                | -10              | 36.8             | 127                            | 86                              | 55                     | 95.9        | 181.7       |
| CV01EM020  | 250 µg<br>(18-55 years) | 1                 | 1                | 36.2             | 124                            | 89                              | 58                     | .           | .           |
| CV01EM020  | 250 µg<br>(18-55 years) | 8                 | 7                | 37.1             | 122                            | 87                              | 60                     | .           | .           |
| CV01EM020  | 250 µg<br>(18-55 years) | 15                | 14               | 36.8             | 121                            | 82                              | 72                     | .           | .           |
| CV01EM020  | 250 µg<br>(18-55 years) | 29                | 29               | 36.8             | 130                            | 87                              | 68                     | .           | .           |
| CV01EM020  | 250 µg<br>(18-55 years) | 36                | 35               | 36.5             | 114                            | 86                              | 72                     | .           | .           |
| CV01EM020  | 250 µg<br>(18-55 years) | 43                | 43               | 36.4             | 120                            | 86                              | 64                     | .           | .           |
| CV01EM020  | 250 µg<br>(18-55 years) | 57                | 56               | 37.1             | 131                            | 90                              | 72                     | .           | .           |
| CV01EM020  | 250 µg<br>(18-55 years) | 119               | 116              | 36.9             | 127                            | 88                              | 63                     | .           | .           |
| CV01EM023  | 100 µg<br>(56-70 years) | -1                | -6               | 36.2             | 150 (Mild)                     | 85                              | 69                     | 81.5        | 177         |
| CV01EM023  | 100 µg<br>(56-70 years) | 1                 | 1                | 36.5             | 150 (Mild)                     | 82                              | 71                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01EM023  | 100 µg<br>(56-70 years) | 8                 | 7                | 36.6             | 145 (Mild)                     | 79                              | 69                     | .           | .           |
| CV01EM023  | 100 µg<br>(56-70 years) | 15                | 14               | 36.4             | 139                            | 83                              | 68                     | .           | .           |
| CV01EM023  | 100 µg<br>(56-70 years) | 29                | 28               | 36.8             | 130                            | 83                              | 63                     | .           | .           |
| CV01EM023  | 100 µg<br>(56-70 years) | 36                | 36               | 36.2             | 126                            | 85                              | 72                     | .           | .           |
| CV01EM023  | 100 µg<br>(56-70 years) | 43                | 42               | 36.9             | 116                            | 75                              | 72                     | .           | .           |
| CV01EM023  | 100 µg<br>(56-70 years) | 57                | 56               | 36.3             | 125                            | 71                              | 55                     | .           | .           |
| CV01EM023  | 100 µg<br>(56-70 years) | 119               | 112              | 36.4             | 121                            | 75                              | 65                     | .           | .           |
| CV01EM024  | 100 µg<br>(56-70 years) | -1                | -4               | 36.9             | 122                            | 79                              | 83                     | 83.3        | 174.5       |
| CV01EM024  | 100 µg<br>(56-70 years) | 1                 | 1                | 36.3             | 120                            | 75                              | 99                     | .           | .           |
| CV01EM024  | 100 µg<br>(56-70 years) | 8                 | 9                | 36.4             | 123                            | 77                              | 82                     | .           | .           |
| CV01EM024  | 100 µg<br>(56-70 years) | 15                | 15               | 36.5             | 109                            | 76                              | 94                     | .           | .           |
| CV01EM024  | 100 µg<br>(56-70 years) | 29                | 30               | 36.4             | 112                            | 67                              | 96                     | .           | .           |
| CV01EM024  | 100 µg<br>(56-70 years) | 36                | 38               | 36.2             | 122                            | 81                              | 100                    | .           | .           |
| CV01EM024  | 100 µg<br>(56-70 years) | 43                | 44               | 36.8             | 123                            | 75                              | 92                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01EM024  | 100 µg<br>(56-70 years) | 57                | 58               | 36.6             | 123                            | 79                              | 89                     | .           | .           |
| CV01EM024  | 100 µg<br>(56-70 years) | 119               | 113              | 36.6             | 131                            | 81                              | 65                     | .           | .           |
| CV01EM025  | 25 µg<br>(56-70 years)  | -1                | -4               | 37.3             | 136                            | 81                              | 80                     | 72.2        | 158.1       |
| CV01EM025  | 25 µg<br>(56-70 years)  | 1                 | 1                | 37.2             | 113                            | 77                              | 82                     | .           | .           |
| CV01EM025  | 25 µg<br>(56-70 years)  | 8                 | 8                | 37.2             | 128                            | 71                              | 80                     | .           | .           |
| CV01EM025  | 25 µg<br>(56-70 years)  | 15                | 15               | 36.2             | 132                            | 71                              | 78                     | .           | .           |
| CV01EM025  | 25 µg<br>(56-70 years)  | 29                | 29               | 36.6             | 119                            | 73                              | 79                     | .           | .           |
| CV01EM025  | 25 µg<br>(56-70 years)  | 36                | 37               | 37.5             | 130                            | 78                              | 78                     | .           | .           |
| CV01EM025  | 25 µg<br>(56-70 years)  | 43                | 43               | 36.8             | 135                            | 73                              | 79                     | .           | .           |
| CV01EM025  | 25 µg<br>(56-70 years)  | 57                | 57               | 36.8             | 124                            | 77                              | 81                     | .           | .           |
| CV01EM025  | 25 µg<br>(56-70 years)  | 119               | 113              | 36.6             | 132                            | 77                              | 86                     | .           | .           |
| CV01EM027  | 25 µg<br>(56-70 years)  | -1                | -4               | 36.8             | 138                            | 78                              | 56                     | 64.7        | 166.5       |
| CV01EM027  | 25 µg<br>(56-70 years)  | 1                 | 1                | 36.3             | 109                            | 66                              | 66                     | .           | .           |
| CV01EM027  | 25 µg<br>(56-70 years)  | 8                 | 8                | 36.8             | 111                            | 69                              | 70                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01EM027  | 25 µg<br>(56-70 years) | 15                | 15               | 36.3             | 92                             | 53                              | 63                     | .           | .           |
| CV01EM027  | 25 µg<br>(56-70 years) | 29                | 29               | 36.7             | 102                            | 60                              | 62                     | .           | .           |
| CV01EM027  | 25 µg<br>(56-70 years) | 36                | 37               | 36.6             | 111                            | 73                              | 61                     | .           | .           |
| CV01EM027  | 25 µg<br>(56-70 years) | 43                | 43               | 36.8             | 126                            | 75                              | 57                     | .           | .           |
| CV01EM027  | 25 µg<br>(56-70 years) | 57                | 57               | 36.8             | 105                            | 62                              | 61                     | .           | .           |
| CV01EM027  | 25 µg<br>(56-70 years) | 119               | 117              | 36.4             | 108                            | 74                              | 62                     | .           | .           |
| CV01EM029  | 25 µg<br>(56-70 years) | -1                | -4               | 36.4             | 138                            | 84                              | 81                     | 52          | 149         |
| CV01EM029  | 25 µg<br>(56-70 years) | 1                 | 1                | 37               | 140                            | 86                              | 78                     | .           | .           |
| CV01EM029  | 25 µg<br>(56-70 years) | 8                 | 8                | 36.6             | 134                            | 80                              | 86                     | .           | .           |
| CV01EM029  | 25 µg<br>(56-70 years) | 15                | 16               | 36.1             | 134                            | 78                              | 80                     | .           | .           |
| CV01EM029  | 25 µg<br>(56-70 years) | 29                | 29               | 37               | 113                            | 72                              | 70                     | .           | .           |
| CV01EM029  | 25 µg<br>(56-70 years) | 36                | 37               | 36.8             | 134                            | 83                              | 73                     | .           | .           |
| CV01EM029  | 25 µg<br>(56-70 years) | 43                | 43               | 36.6             | 128                            | 80                              | 73                     | .           | .           |
| CV01EM029  | 25 µg<br>(56-70 years) | 57                | 57               | 37               | 124                            | 76                              | 77                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01EM029  | 25 µg<br>(56-70 years)  | 119               | 124              | 36.8             | 120                            | 67                              | 73                     | .           | .           |
| CV01EM030  | 25 µg<br>(56-70 years)  | -1                | -4               | 36.5             | 115                            | 72                              | 41 (Severe)            | 88.6        | 186         |
| CV01EM030  | 25 µg<br>(56-70 years)  | 1                 | 1                | 37               | 143 (Mild)                     | 79                              | 74                     | .           | .           |
| CV01EM030  | 25 µg<br>(56-70 years)  | 8                 | 8                | 36.6             | 122                            | 74                              | 68                     | .           | .           |
| CV01EM030  | 25 µg<br>(56-70 years)  | 15                | 15               | 36.6             | 102                            | 55                              | 61                     | .           | .           |
| CV01EM030  | 25 µg<br>(56-70 years)  | 29                | 30               | 36.3             | 116                            | 69                              | 61                     | .           | .           |
| CV01EM030  | 25 µg<br>(56-70 years)  | 36                | 37               | 36.3             | 107                            | 64                              | 60                     | .           | .           |
| CV01EM030  | 25 µg<br>(56-70 years)  | 43                | 45               | 36.3             | 115                            | 74                              | 65                     | .           | .           |
| CV01EM030  | 25 µg<br>(56-70 years)  | 57                | 58               | 36.4             | 103                            | 66                              | 55                     | .           | .           |
| CV01EM030  | 25 µg<br>(56-70 years)  | 119               | 115              | 36.7             | 106                            | 48                              | 71                     | .           | .           |
| CV01EM032  | 100 µg<br>(56-70 years) | -1                | -4               | 36.7             | 110                            | 72                              | 78                     | 56.4        | 164.5       |
| CV01EM032  | 100 µg<br>(56-70 years) | 1                 | 1                | 36.9             | 101                            | 71                              | 89                     | .           | .           |
| CV01EM032  | 100 µg<br>(56-70 years) | 8                 | 7                | 37.3             | 113                            | 70                              | 88                     | .           | .           |
| CV01EM032  | 100 µg<br>(56-70 years) | 15                | 14               | 37.2             | 109                            | 75                              | 86                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01EM032  | 100 µg<br>(56-70 years) | 29                | 28               | 37.1             | 110                            | 75                              | 90                     | .           | .           |
| CV01EM032  | 100 µg<br>(56-70 years) | 36                | 36               | 36.7             | 105                            | 68                              | 88                     | .           | .           |
| CV01EM032  | 100 µg<br>(56-70 years) | 43                | 44               | 37.2             | 103                            | 67                              | 86                     | .           | .           |
| CV01EM032  | 100 µg<br>(56-70 years) | 57                | 58               | 36.3             | 103                            | 67                              | 78                     | .           | .           |
| CV01EM032  | 100 µg<br>(56-70 years) | 119               | 114              | 37.1             | 110                            | 63                              | 81                     | .           | .           |
| CV01EM033  | 100 µg<br>(56-70 years) | -1                | -4               | 36.4             | 147 (Mild)                     | 93 (Mild)                       | 75                     | 64.2        | 160.1       |
| CV01EM033  | 100 µg<br>(56-70 years) | 1                 | 1                | 36.5             | 150 (Mild)                     | 93 (Mild)                       | 75                     | .           | .           |
| CV01EM033  | 100 µg<br>(56-70 years) | 8                 | 8                | 36.1             | 142 (Mild)                     | 89                              | 83                     | .           | .           |
| CV01EM033  | 100 µg<br>(56-70 years) | 15                | 15               | 36.4             | 142 (Mild)                     | 92 (Mild)                       | 85                     | .           | .           |
| CV01EM033  | 100 µg<br>(56-70 years) | 29                | 29               | 36.3             | 146 (Mild)                     | 91 (Mild)                       | 72                     | .           | .           |
| CV01EM033  | 100 µg<br>(56-70 years) | 36                | 36               | 36.8             | 145 (Mild)                     | 87                              | 71                     | .           | .           |
| CV01EM033  | 100 µg<br>(56-70 years) | 43                | 42               | 36.3             | 135                            | 89                              | 71                     | .           | .           |
| CV01EM033  | 100 µg<br>(56-70 years) | 57                | 56               | 36.1             | 134                            | 87                              | 77                     | .           | .           |
| CV01EM033  | 100 µg<br>(56-70 years) | 119               | 112              | 36.3             | 136                            | 90                              | 60                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01EM039  | 100 µg<br>(56-70 years) | -1                | -4               | 37.2             | 134                            | 87                              | 60                     | 66.5        | 171         |
| CV01EM039  | 100 µg<br>(56-70 years) | 1                 | 1                | 36.4             | 130                            | 84                              | 66                     | .           | .           |
| CV01EM039  | 100 µg<br>(56-70 years) | 8                 | 8                | 37               | 120                            | 79                              | 71                     | .           | .           |
| CV01EM039  | 100 µg<br>(56-70 years) | 15                | 15               | 36.6             | 116                            | 78                              | 77                     | .           | .           |
| CV01EM039  | 100 µg<br>(56-70 years) | 29                | 29               | 37.1             | 126                            | 88                              | 75                     | .           | .           |
| CV01EM039  | 100 µg<br>(56-70 years) | 36                | 37               | 37.1             | 121                            | 84                              | 76                     | .           | .           |
| CV01EM039  | 100 µg<br>(56-70 years) | 43                | 45               | 36.9             | 119                            | 81                              | 68                     | .           | .           |
| CV01EM039  | 100 µg<br>(56-70 years) | 57                | 58               | 36.7             | 110                            | 71                              | 64                     | .           | .           |
| CV01EM039  | 100 µg<br>(56-70 years) | 119               | 112              | 37               | 150 (Mild)                     | 90                              | 55                     | .           | .           |
| CV01EM041  | 25 µg<br>(56-70 years)  | -1                | -2               | 36.4             | 121                            | 79                              | 58                     | 62          | 163.1       |
| CV01EM041  | 25 µg<br>(56-70 years)  | 1                 | 1                | 37.1             | 113                            | 71                              | 72                     | .           | .           |
| CV01EM041  | 25 µg<br>(56-70 years)  | 8                 | 9                | 36.3             | 104                            | 64                              | 62                     | .           | .           |
| CV01EM041  | 25 µg<br>(56-70 years)  | 15                | 16               | 36.4             | 113                            | 68                              | 63                     | .           | .           |
| CV01EM041  | 25 µg<br>(56-70 years)  | 29                | 30               | 36.8             | 124                            | 69                              | 61                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01EM041  | 25 µg<br>(56-70 years)  | 36                | 37               | 36.8             | 117                            | 80                              | 57                     | .           | .           |
| CV01EM041  | 25 µg<br>(56-70 years)  | 43                | 45               | 36.6             | 127                            | 81                              | 78                     | .           | .           |
| CV01EM041  | 25 µg<br>(56-70 years)  | 57                | 58               | 36.3             | 125                            | 78                              | 68                     | .           | .           |
| CV01EM041  | 25 µg<br>(56-70 years)  | 119               | 117              | 36.6             | 124                            | 79                              | 64                     | .           | .           |
| CV01EM045  | 100 µg<br>(56-70 years) | -1                | -6               | 36.3             | 129                            | 74                              | 53 (Mild)              | 60.6        | 167.7       |
| CV01EM045  | 100 µg<br>(56-70 years) | 1                 | 1                | 36.9             | 129                            | 81                              | 62                     | .           | .           |
| CV01EM045  | 100 µg<br>(56-70 years) | 8                 | 7                | 36.5             | 116                            | 70                              | 65                     | .           | .           |
| CV01EM045  | 100 µg<br>(56-70 years) | 15                | 14               | 36.9             | 113                            | 71                              | 64                     | .           | .           |
| CV01EM045  | 100 µg<br>(56-70 years) | 29                | 28               | 37.4             | 128                            | 72                              | 67                     | .           | .           |
| CV01EM045  | 100 µg<br>(56-70 years) | 36                | 35               | 36.7             | 112                            | 71                              | 68                     | .           | .           |
| CV01EM045  | 100 µg<br>(56-70 years) | 43                | 42               | 36.9             | 106                            | 69                              | 63                     | .           | .           |
| CV01EM045  | 100 µg<br>(56-70 years) | 57                | 56               | 36.6             | 123                            | 75                              | 56                     | .           | .           |
| CV01EM045  | 100 µg<br>(56-70 years) | 119               | 114              | 36.6             | 122                            | 70                              | 62                     | .           | .           |
| CV01EM049  | 50 µg<br>(18-55 years)  | -1                | -1               | 36.5             | 134                            | 85                              | 48 (Moderate)          | 108         | 188.8       |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01EM049  | 50 µg<br>(18-55 years) | 1                 | 1                | 36.6             | 127                            | 76                              | 50 (Mild)              | .           | .           |
| CV01EM049  | 50 µg<br>(18-55 years) | 8                 | 7                | 36.7             | 126                            | 74                              | 52 (Mild)              | .           | .           |
| CV01EM049  | 50 µg<br>(18-55 years) | 15                | 13               | 36.7             | 135                            | 88                              | 55                     | .           | .           |
| CV01EM049  | 50 µg<br>(18-55 years) | 29                | 29               | 36.6             | 127                            | 78                              | 50 (Mild)              | .           | .           |
| CV01EM049  | 50 µg<br>(18-55 years) | 36                | 35               | 36.7             | 126                            | 76                              | 55                     | .           | .           |
| CV01EM049  | 50 µg<br>(18-55 years) | 43                | 41               | 36.7             | 132                            | 78                              | 53 (Mild)              | .           | .           |
| CV01EM049  | 50 µg<br>(18-55 years) | 57                | 55               | 36.4             | 118                            | 69                              | 50 (Mild)              | .           | .           |
| CV01EM049  | 50 µg<br>(18-55 years) | 119               | 112              | 36.4             | 136                            | 85                              | 53 (Mild)              | .           | .           |
| CV01EM051  | 50 µg<br>(18-55 years) | -1                | -1               | 36.8             | 111                            | 74                              | 66                     | 73          | 171         |
| CV01EM051  | 50 µg<br>(18-55 years) | 1                 | 1                | 36.9             | 106                            | 72                              | 89                     | .           | .           |
| CV01EM051  | 50 µg<br>(18-55 years) | 8                 | 8                | 36.2             | 97                             | 67                              | 70                     | .           | .           |
| CV01EM051  | 50 µg<br>(18-55 years) | 15                | 14               | 36.5             | 116                            | 76                              | 80                     | .           | .           |
| CV01EM051  | 50 µg<br>(18-55 years) | 29                | 27               | 36.6             | 103                            | 71                              | 68                     | .           | .           |
| CV01EM051  | 50 µg<br>(18-55 years) | 36                | 35               | 36.5             | 111                            | 75                              | 75                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01EM051  | 50 µg<br>(18-55 years) | 43                | 41               | 37               | 112                            | 73                              | 77                     | .           | .           |
| CV01EM051  | 50 µg<br>(18-55 years) | 57                | 62               | 37.2             | 107                            | 74                              | 71                     | .           | .           |
| CV01EM051  | 50 µg<br>(18-55 years) | 119               | 112              | 36.7             | 100                            | 64                              | 76                     | .           | .           |
| CV01EM053  | 50 µg<br>(18-55 years) | -1                | -1               | 37.3             | 121                            | 90                              | 91                     | 50.9        | 166         |
| CV01EM053  | 50 µg<br>(18-55 years) | 1                 | 1                | 37.2             | 113                            | 77                              | 90                     | .           | .           |
| CV01EM053  | 50 µg<br>(18-55 years) | 8                 | 9                | 36.9             | 116                            | 81                              | 67                     | .           | .           |
| CV01EM053  | 50 µg<br>(18-55 years) | 15                | 13               | 36.9             | 114                            | 79                              | 87                     | .           | .           |
| CV01EM053  | 50 µg<br>(18-55 years) | 29                | 27               | 36.9             | 115                            | 79                              | 80                     | .           | .           |
| CV01EM053  | 50 µg<br>(18-55 years) | 36                | 35               | 37.1             | 105                            | 74                              | 85                     | .           | .           |
| CV01EM053  | 50 µg<br>(18-55 years) | 43                | 43               | 36.3             | 106                            | 76                              | 80                     | .           | .           |
| CV01EM053  | 50 µg<br>(18-55 years) | 57                | 54               | 36.9             | 104                            | 74                              | 89                     | .           | .           |
| CV01EM053  | 50 µg<br>(18-55 years) | 119               | 117              | 36.4             | 119                            | 74                              | 85                     | .           | .           |
| CV01EM054  | 50 µg<br>(18-55 years) | -1                | -1               | 37               | 120                            | 85                              | 76                     | 61.8        | 163.5       |
| CV01EM054  | 50 µg<br>(18-55 years) | 1                 | 1                | 36.3             | 111                            | 72                              | 76                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01EM054  | 50 µg<br>(18-55 years)  | 8                 | 9                | 36.6             | 116                            | 77                              | 67                     | .           | .           |
| CV01EM054  | 50 µg<br>(18-55 years)  | 15                | 14               | 37               | 124                            | 80                              | 59                     | .           | .           |
| CV01EM054  | 50 µg<br>(18-55 years)  | 29                | 27               | 36.3             | 118                            | 74                              | 67                     | .           | .           |
| CV01EM054  | 50 µg<br>(18-55 years)  | 36                | 35               | 36.8             | 113                            | 79                              | 66                     | .           | .           |
| CV01EM054  | 50 µg<br>(18-55 years)  | 43                | 42               | 36.7             | 108                            | 68                              | 68                     | .           | .           |
| CV01EM054  | 50 µg<br>(18-55 years)  | 57                | 54               | 36.7             | 125                            | 89                              | 71                     | .           | .           |
| CV01EM054  | 50 µg<br>(18-55 years)  | 119               | 112              | 36.2             | 117                            | 76                              | 61                     | .           | .           |
| CV01HC001  | 100 µg<br>(18-55 years) | -1                | -3               | 36.8             | 122                            | 77                              | 77                     | 78.5        | 167.9       |
| CV01HC001  | 100 µg<br>(18-55 years) | 1                 | 1                | 36.8             | 119                            | 58                              | 70                     | .           | .           |
| CV01HC001  | 100 µg<br>(18-55 years) | 8                 | 8                | 36.8             | 126                            | 73                              | 85                     | .           | .           |
| CV01HC001  | 100 µg<br>(18-55 years) | 15                | 13               | 36.7             | 112                            | 68                              | 80                     | .           | .           |
| CV01HC001  | 100 µg<br>(18-55 years) | 29                | 29               | 36.9             | 113                            | 79                              | 91                     | .           | .           |
| CV01HC001  | 100 µg<br>(18-55 years) | 36                | 35               | 37.2             | 118                            | 67                              | 73                     | .           | .           |
| CV01HC001  | 100 µg<br>(18-55 years) | 43                | 41               | 36.9             | 117                            | 68                              | 86                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01HC001  | 100 µg<br>(18-55 years) | 57                | 55               | 36.8             | 125                            | 72                              | 98                     | .           | .           |
| CV01HC001  | 100 µg<br>(18-55 years) | 119               | 113              | 37.1             | 118                            | 72                              | 77                     | .           | .           |
| CV01HC003  | 100 µg<br>(18-55 years) | -1                | -3               | 36.7             | 129                            | 71                              | 67                     | 98.7        | 188         |
| CV01HC003  | 100 µg<br>(18-55 years) | 1                 | 1                | 37.1             | 136                            | 75                              | 81                     | .           | .           |
| CV01HC003  | 100 µg<br>(18-55 years) | 8                 | 9                | 36.7             | 137                            | 73                              | 83                     | .           | .           |
| CV01HC003  | 100 µg<br>(18-55 years) | 15                | 15               | 36.6             | 116                            | 73                              | 83                     | .           | .           |
| CV01HC003  | 100 µg<br>(18-55 years) | 29                | 29               | 36.6             | 125                            | 74                              | 75                     | .           | .           |
| CV01HC003  | 100 µg<br>(18-55 years) | 36                | 35               | 36.7             | 119                            | 74                              | 81                     | .           | .           |
| CV01HC003  | 100 µg<br>(18-55 years) | 119               | 127              | 36.9             | 137                            | 85                              | 88                     | .           | .           |
| CV01HC004  | 100 µg<br>(18-55 years) | -1                | -3               | 36.8             | 140                            | 92 (Mild)                       | 85                     | 81.6        | 172.7       |
| CV01HC004  | 100 µg<br>(18-55 years) | 1                 | 1                | 36.7             | 138                            | 83                              | 85                     | .           | .           |
| CV01HC004  | 100 µg<br>(18-55 years) | 8                 | 8                | 36.7             | 136                            | 84                              | 85                     | .           | .           |
| CV01HC004  | 100 µg<br>(18-55 years) | 15                | 15               | 37               | 138                            | 90                              | 86                     | .           | .           |
| CV01HC004  | 100 µg<br>(18-55 years) | 29                | 29               | 36.7             | 123                            | 87                              | 68                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01HC004  | 100 µg<br>(18-55 years) | 36                | 36               | 37.1             | 136                            | 87                              | 84                     | .           | .           |
| CV01HC004  | 100 µg<br>(18-55 years) | 43                | 43               | 36.8             | 129                            | 77                              | 70                     | .           | .           |
| CV01HC004  | 100 µg<br>(18-55 years) | 57                | 57               | 36.9             | 139                            | 81                              | 94                     | .           | .           |
| CV01HC004  | 100 µg<br>(18-55 years) | 119               | 125              | 36.3             | 140                            | 81                              | 92                     | .           | .           |
| CV01HC007  | 100 µg<br>(18-55 years) | -1                | -2               | 36.7             | 142 (Mild)                     | 70                              | 78                     | 77.1        | 177.8       |
| CV01HC007  | 100 µg<br>(18-55 years) | 1                 | 1                | 36.6             | 120                            | 77                              | 88                     | .           | .           |
| CV01HC007  | 100 µg<br>(18-55 years) | 8                 | 8                | 36.7             | 129                            | 68                              | 80                     | .           | .           |
| CV01HC007  | 100 µg<br>(18-55 years) | 15                | 14               | 36.7             | 113                            | 76                              | 70                     | .           | .           |
| CV01HC007  | 100 µg<br>(18-55 years) | 29                | 28               | 36.7             | 125                            | 80                              | 80                     | .           | .           |
| CV01HC007  | 100 µg<br>(18-55 years) | 36                | 35               | 36.7             | 140                            | 71                              | 91                     | .           | .           |
| CV01HC007  | 100 µg<br>(18-55 years) | 43                | 42               | 36.8             | 124                            | 77                              | 72                     | .           | .           |
| CV01HC007  | 100 µg<br>(18-55 years) | 57                | 56               | 36.6             | 126                            | 79                              | 70                     | .           | .           |
| CV01HC007  | 100 µg<br>(18-55 years) | 119               | 112              | 36.7             | 133                            | 80                              | 70                     | .           | .           |
| CV01HC008  | 100 µg<br>(18-55 years) | -1                | -4               | 36.4             | 119                            | 83                              | 56                     | 87          | 172.7       |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01HC008  | 100 µg<br>(18-55 years) | 1                 | 1                | 36.8             | 117                            | 82                              | 69                     | .           | .           |
| CV01HC008  | 100 µg<br>(18-55 years) | 8                 | 8                | 36.7             | 110                            | 76                              | 63                     | .           | .           |
| CV01HC008  | 100 µg<br>(18-55 years) | 15                | 15               | 36.6             | 111                            | 64                              | 55                     | .           | .           |
| CV01HC008  | 100 µg<br>(18-55 years) | 29                | 29               | 36.4             | 107                            | 68                              | 55                     | .           | .           |
| CV01HC008  | 100 µg<br>(18-55 years) | 36                | 36               | 36.5             | 110                            | 67                              | 56                     | .           | .           |
| CV01HC008  | 100 µg<br>(18-55 years) | 43                | 43               | 36.6             | 109                            | 77                              | 60                     | .           | .           |
| CV01HC008  | 100 µg<br>(18-55 years) | 57                | 58               | 36.6             | 134                            | 73                              | 65                     | .           | .           |
| CV01HC008  | 100 µg<br>(18-55 years) | .                 | 59               | 36.8             | 113                            | 80                              | 64                     | .           | .           |
| CV01HC008  | 100 µg<br>(18-55 years) | 119               | 120              | 36.3             | 119                            | 74                              | 61                     | .           | .           |
| CV01HC012  | 250 µg<br>(18-55 years) | -1                | -14              | 36.4             | 109                            | 70                              | 66                     | 64.5        | 165.1       |
| CV01HC012  | 250 µg<br>(18-55 years) | 1                 | 1                | 36.5             | 106                            | 52                              | 66                     | .           | .           |
| CV01HC012  | 250 µg<br>(18-55 years) | 8                 | 7                | 36.3             | 147 (Mild)                     | 86                              | 80                     | .           | .           |
| CV01HC012  | 250 µg<br>(18-55 years) | 15                | 14               | 36.8             | 108                            | 60                              | 76                     | .           | .           |
| CV01HC012  | 250 µg<br>(18-55 years) | 29                | 29               | 36.6             | 115                            | 72                              | 69                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01HC012  | 250 µg<br>(18-55 years) | 36                | 36               | 36.7             | 114                            | 61                              | 79                     | .           | .           |
| CV01HC012  | 250 µg<br>(18-55 years) | 43                | 43               | 36.5             | 108                            | 64                              | 77                     | .           | .           |
| CV01HC012  | 250 µg<br>(18-55 years) | 57                | 56               | 36.5             | 106                            | 63                              | 69                     | .           | .           |
| CV01HC012  | 250 µg<br>(18-55 years) | 119               | 119              | 36.1             | 96                             | 55                              | 77                     | .           | .           |
| CV01HC013  | 250 µg<br>(18-55 years) | -1                | -14              | 36.7             | 103                            | 58                              | 58                     | 70.6        | 154.9       |
| CV01HC013  | 250 µg<br>(18-55 years) | 1                 | 1                | 36.6             | 118                            | 57                              | 68                     | .           | .           |
| CV01HC013  | 250 µg<br>(18-55 years) | 8                 | 8                | 36.6             | 104                            | 56                              | 59                     | .           | .           |
| CV01HC013  | 250 µg<br>(18-55 years) | 15                | 15               | 36.7             | 100                            | 67                              | 74                     | .           | .           |
| CV01HC013  | 250 µg<br>(18-55 years) | 29                | 29               | 36.9             | 112                            | 58                              | 61                     | .           | .           |
| CV01HC013  | 250 µg<br>(18-55 years) | 36                | 36               | 36.8             | 113                            | 56                              | 61                     | .           | .           |
| CV01HC013  | 250 µg<br>(18-55 years) | 43                | 43               | 37.1             | 102                            | 65                              | 62                     | .           | .           |
| CV01HC013  | 250 µg<br>(18-55 years) | 57                | 58               | 36.8             | 111                            | 66                              | 65                     | .           | .           |
| CV01HC013  | 250 µg<br>(18-55 years) | 119               | 119              | 37               | 112                            | 62                              | 67                     | .           | .           |
| CV01HC016  | 250 µg<br>(18-55 years) | -1                | -13              | 36.8             | 116                            | 71                              | 68                     | 74.1        | 162.6       |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01HC016  | 250 µg<br>(18-55 years) | 1                 | 1                | 36.9             | 117                            | 62                              | 76                     | .           | .           |
| CV01HC016  | 250 µg<br>(18-55 years) | 8                 | 8                | 37.2             | 110                            | 63                              | 79                     | .           | .           |
| CV01HC016  | 250 µg<br>(18-55 years) | 15                | 14               | 36.8             | 112                            | 69                              | 85                     | .           | .           |
| CV01HC016  | 250 µg<br>(18-55 years) | 29                | 28               | 37.1             | 112                            | 61                              | 73                     | .           | .           |
| CV01HC016  | 250 µg<br>(18-55 years) | 36                | 35               | 37.1             | 112                            | 65                              | 70                     | .           | .           |
| CV01HC016  | 250 µg<br>(18-55 years) | 43                | 43               | 37.2             | 114                            | 58                              | 77                     | .           | .           |
| CV01HC016  | 250 µg<br>(18-55 years) | 57                | 56               | 37.3             | 111                            | 60                              | 72                     | .           | .           |
| CV01HC016  | 250 µg<br>(18-55 years) | 119               | 116              | 37.3             | 122                            | 57                              | 66                     | .           | .           |
| CV01HC026  | 25 µg<br>(56-70 years)  | -1                | -1               | 36.9             | 115                            | 67                              | 69                     | 82.9        | 167.6       |
| CV01HC026  | 25 µg<br>(56-70 years)  | 1                 | 1                | 36.8             | 100                            | 58                              | 79                     | .           | .           |
| CV01HC026  | 25 µg<br>(56-70 years)  | 8                 | 7                | 36.8             | 112                            | 61                              | 75                     | .           | .           |
| CV01HC026  | 25 µg<br>(56-70 years)  | .                 | 9                | 36.7             | 119                            | 71                              | 77                     | .           | .           |
| CV01HC026  | 25 µg<br>(56-70 years)  | 15                | 14               | 36.9             | 114                            | 69                              | 70                     | .           | .           |
| CV01HC026  | 25 µg<br>(56-70 years)  | 29                | 29               | 36.8             | 111                            | 68                              | 72                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01HC026  | 25 µg<br>(56-70 years)  | 36                | 35               | 36.8             | 115                            | 56                              | 62                     | .           | .           |
| CV01HC026  | 25 µg<br>(56-70 years)  | 43                | 42               | 36.9             | 102                            | 66                              | 71                     | .           | .           |
| CV01HC026  | 25 µg<br>(56-70 years)  | 57                | 56               | 36.8             | 101                            | 67                              | 75                     | .           | .           |
| CV01HC026  | 25 µg<br>(56-70 years)  | 119               | 112              | 36.5             | 121                            | 69                              | 71                     | .           | .           |
| CV01HC027  | 25 µg<br>(56-70 years)  | -1                | -1               | 36.8             | 142 (Mild)                     | 72                              | 66                     | 67.8        | 167.6       |
| CV01HC027  | 25 µg<br>(56-70 years)  | 1                 | 1                | 36.9             | 118                            | 64                              | 75                     | .           | .           |
| CV01HC027  | 25 µg<br>(56-70 years)  | 8                 | 8                | 37.1             | 138                            | 70                              | 65                     | .           | .           |
| CV01HC027  | 25 µg<br>(56-70 years)  | 15                | 15               | 37               | 123                            | 61                              | 69                     | .           | .           |
| CV01HC027  | 25 µg<br>(56-70 years)  | 29                | 29               | 36.8             | 118                            | 59                              | 70                     | .           | .           |
| CV01HC027  | 25 µg<br>(56-70 years)  | 36                | 36               | 36.7             | 129                            | 65                              | 70                     | .           | .           |
| CV01HC027  | 25 µg<br>(56-70 years)  | 43                | 43               | 37.1             | 122                            | 63                              | 71                     | .           | .           |
| CV01HC027  | 25 µg<br>(56-70 years)  | 57                | 61               | 37               | 117                            | 65                              | 72                     | .           | .           |
| CV01HC027  | 25 µg<br>(56-70 years)  | 119               | 120              | 35.8             | 117                            | 67                              | 67                     | .           | .           |
| CV01HC031  | 100 µg<br>(56-70 years) | -1                | -5               | 36.6             | 124                            | 78                              | 59                     | 71.1        | 167.6       |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01HC031  | 100 µg<br>(56-70 years) | 1                 | 1                | 36.6             | 120                            | 84                              | 61                     | .           | .           |
| CV01HC031  | 100 µg<br>(56-70 years) | 8                 | 8                | 36.6             | 140                            | 78                              | 76                     | .           | .           |
| CV01HC031  | 100 µg<br>(56-70 years) | 15                | 15               | 36.8             | 139                            | 80                              | 60                     | .           | .           |
| CV01HC031  | 100 µg<br>(56-70 years) | 29                | 29               | 37.1             | 132                            | 79                              | 57                     | .           | .           |
| CV01HC031  | 100 µg<br>(56-70 years) | 36                | 36               | 36.8             | 124                            | 81                              | 64                     | .           | .           |
| CV01HC031  | 100 µg<br>(56-70 years) | 43                | 43               | 36.8             | 133                            | 84                              | 64                     | .           | .           |
| CV01HC031  | 100 µg<br>(56-70 years) | 57                | 57               | 36.6             | 138                            | 80                              | 56                     | .           | .           |
| CV01HC031  | 100 µg<br>(56-70 years) | 119               | 115              | 35.9             | 139                            | 83                              | 55                     | .           | .           |
| CV01HC032  | 25 µg<br>(56-70 years)  | -1                | -4               | 36.8             | 140                            | 80                              | 85                     | 89.8        | 180.3       |
| CV01HC032  | 25 µg<br>(56-70 years)  | 1                 | 1                | 36.9             | 150 (Mild)                     | 76                              | 68                     | .           | .           |
| CV01HC032  | 25 µg<br>(56-70 years)  | 8                 | 8                | 36.8             | 140                            | 78                              | 88                     | .           | .           |
| CV01HC032  | 25 µg<br>(56-70 years)  | 15                | 15               | 36.7             | 110                            | 75                              | 68                     | .           | .           |
| CV01HC032  | 25 µg<br>(56-70 years)  | 29                | 29               | 36.8             | 141 (Mild)                     | 87                              | 97                     | .           | .           |
| CV01HC032  | 25 µg<br>(56-70 years)  | 36                | 37               | 36.8             | 134                            | 74                              | 82                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01HC032  | 25 µg<br>(56-70 years)  | 43                | 43               | 36.8             | 130                            | 63                              | 97                     | .           | .           |
| CV01HC032  | 25 µg<br>(56-70 years)  | 57                | 57               | 36.8             | 132                            | 62                              | 96                     | .           | .           |
| CV01HC032  | 25 µg<br>(56-70 years)  | 119               | 113              | 36.9             | 152 (Moderate)                 | 84                              | 94                     | .           | .           |
| CV01HC033  | 25 µg<br>(56-70 years)  | -1                | -4               | 36.6             | 150 (Mild)                     | 92 (Mild)                       | 68                     | 68.7        | 175.3       |
| CV01HC033  | 25 µg<br>(56-70 years)  | 1                 | 1                | 36.6             | 146 (Mild)                     | 92 (Mild)                       | 64                     | .           | .           |
| CV01HC033  | 25 µg<br>(56-70 years)  | 8                 | 8                | 36.5             | 148 (Mild)                     | 80                              | 69                     | .           | .           |
| CV01HC033  | 25 µg<br>(56-70 years)  | 15                | 15               | 36.6             | 140                            | 85                              | 72                     | .           | .           |
| CV01HC033  | 25 µg<br>(56-70 years)  | 29                | 29               | 36.7             | 130                            | 92 (Mild)                       | 68                     | .           | .           |
| CV01HC033  | 25 µg<br>(56-70 years)  | 36                | 37               | 36.8             | 135                            | 90                              | 77                     | .           | .           |
| CV01HC033  | 25 µg<br>(56-70 years)  | 43                | 43               | 36.8             | 138                            | 88                              | 80                     | .           | .           |
| CV01HC033  | 25 µg<br>(56-70 years)  | 57                | 57               | 36.8             | 150 (Mild)                     | 86                              | 66                     | .           | .           |
| CV01HC033  | 25 µg<br>(56-70 years)  | 119               | 120              | 37.2             | 143 (Mild)                     | 91 (Mild)                       | 77                     | .           | .           |
| CV01HC034  | 100 µg<br>(56-70 years) | -1                | -4               | 36.9             | 134                            | 90                              | 60                     | 50.5        | 152.4       |
| CV01HC034  | 100 µg<br>(56-70 years) | 1                 | 1                | 36.6             | 140                            | 92 (Mild)                       | 69                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01HC034  | 100 µg<br>(56-70 years) | 8                 | 8                | 37               | 139                            | 68                              | 79                     | .           | .           |
| CV01HC034  | 100 µg<br>(56-70 years) | 15                | 15               | 36.8             | 153 (Moderate)                 | 87                              | 73                     | .           | .           |
| CV01HC034  | 100 µg<br>(56-70 years) | 29                | 30               | 36.8             | 130                            | 70                              | 84                     | .           | .           |
| CV01HC034  | 100 µg<br>(56-70 years) | 36                | 37               | 36.8             | 140                            | 79                              | 80                     | .           | .           |
| CV01HC034  | 100 µg<br>(56-70 years) | 43                | 43               | 36.7             | 140                            | 82                              | 74                     | .           | .           |
| CV01HC034  | 100 µg<br>(56-70 years) | 57                | 57               | 36.8             | 136                            | 80                              | 72                     | .           | .           |
| CV01HC034  | 100 µg<br>(56-70 years) | 119               | 113              | 35.7             | 121                            | 77                              | 73                     | .           | .           |
| CV01HC035  | 25 µg<br>(56-70 years)  | -1                | -4               | 36.9             | 116                            | 72                              | 68                     | 86          | 182.9       |
| CV01HC035  | 25 µg<br>(56-70 years)  | 1                 | 1                | 36.9             | 114                            | 73                              | 69                     | .           | .           |
| CV01HC035  | 25 µg<br>(56-70 years)  | 8                 | 8                | 36.6             | 115                            | 62                              | 76                     | .           | .           |
| CV01HC035  | 25 µg<br>(56-70 years)  | 15                | 15               | 36.9             | 117                            | 69                              | 77                     | .           | .           |
| CV01HC035  | 25 µg<br>(56-70 years)  | 29                | 29               | 36.9             | 127                            | 77                              | 72                     | .           | .           |
| CV01HC035  | 25 µg<br>(56-70 years)  | 36                | 37               | 37               | 117                            | 59                              | 74                     | .           | .           |
| CV01HC035  | 25 µg<br>(56-70 years)  | 43                | 43               | 36.7             | 125                            | 70                              | 73                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01HC035  | 25 µg<br>(56-70 years)  | 57                | 57               | 36.7             | 121                            | 67                              | 62                     | .           | .           |
| CV01HC035  | 25 µg<br>(56-70 years)  | 119               | 113              | 36.9             | 126                            | 74                              | 76                     | .           | .           |
| CV01HC037  | 100 µg<br>(56-70 years) | -1                | -5               | 36.7             | 101                            | 58                              | 58                     | 64.7        | 171.5       |
| CV01HC037  | 100 µg<br>(56-70 years) | 1                 | 1                | 36.8             | 96                             | 60                              | 64                     | .           | .           |
| CV01HC037  | 100 µg<br>(56-70 years) | 8                 | 8                | 36.9             | 91                             | 63                              | 69                     | .           | .           |
| CV01HC037  | 100 µg<br>(56-70 years) | 15                | 15               | 36.6             | 103                            | 57                              | 69                     | .           | .           |
| CV01HC037  | 100 µg<br>(56-70 years) | 29                | 29               | 36.8             | 105                            | 70                              | 61                     | .           | .           |
| CV01HC037  | 100 µg<br>(56-70 years) | 36                | 36               | 36.9             | 102                            | 62                              | 57                     | .           | .           |
| CV01HC037  | 100 µg<br>(56-70 years) | 43                | 43               | 36.8             | 108                            | 67                              | 58                     | .           | .           |
| CV01HC037  | 100 µg<br>(56-70 years) | 57                | 57               | 36.8             | 104                            | 66                              | 63                     | .           | .           |
| CV01HC037  | 100 µg<br>(56-70 years) | 119               | 121              | 36.8             | 104                            | 59                              | 64                     | .           | .           |
| CV01HC038  | 100 µg<br>(56-70 years) | -1                | -4               | 36.5             | 141 (Mild)                     | 70                              | 74                     | 95.2        | 195.6       |
| CV01HC038  | 100 µg<br>(56-70 years) | 1                 | 1                | 36.6             | 129                            | 74                              | 75                     | .           | .           |
| CV01HC038  | 100 µg<br>(56-70 years) | 8                 | 9                | 36.2             | 130                            | 79                              | 81                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01HC038  | 100 µg<br>(56-70 years) | 15                | 14               | 36.6             | 137                            | 71                              | 76                     | .           | .           |
| CV01HC038  | 100 µg<br>(56-70 years) | 29                | 28               | 36.8             | 128                            | 84                              | 78                     | .           | .           |
| CV01HC038  | 100 µg<br>(56-70 years) | 36                | 36               | 36.8             | 138                            | 80                              | 72                     | .           | .           |
| CV01HC038  | 100 µg<br>(56-70 years) | 43                | 42               | 36.6             | 134                            | 80                              | 70                     | .           | .           |
| CV01HC038  | 100 µg<br>(56-70 years) | 57                | 56               | 36.9             | 132                            | 80                              | 69                     | .           | .           |
| CV01HC038  | 100 µg<br>(56-70 years) | 119               | 112              | 36.5             | 131                            | 78                              | 70                     | .           | .           |
| CV01HC048  | 50 µg<br>(18-55 years)  | -1                | -3               | 36.8             | 133                            | 83                              | 70                     | 92.7        | 182.9       |
| CV01HC048  | 50 µg<br>(18-55 years)  | 1                 | 1                | 36.9             | 126                            | 80                              | 80                     | .           | .           |
| CV01HC048  | 50 µg<br>(18-55 years)  | 8                 | 8                | 36.9             | 135                            | 81                              | 76                     | .           | .           |
| CV01HC048  | 50 µg<br>(18-55 years)  | 15                | 15               | 37.2             | 118                            | 80                              | 88                     | .           | .           |
| CV01HC048  | 50 µg<br>(18-55 years)  | 29                | 29               | 36.9             | 116                            | 73                              | 73                     | .           | .           |
| CV01HC048  | 50 µg<br>(18-55 years)  | 36                | 35               | 36.7             | 129                            | 82                              | 71                     | .           | .           |
| CV01HC048  | 50 µg<br>(18-55 years)  | 57                | 57               | 36.9             | 118                            | 81                              | 62                     | .           | .           |
| CV01HC048  | 50 µg<br>(18-55 years)  | 119               | 121              | 36.8             | 124                            | 84                              | 71                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01HC050  | 50 µg<br>(18-55 years) | -1                | -2               | 36.8             | 101                            | 58                              | 64                     | 60.1        | 172.7       |
| CV01HC050  | 50 µg<br>(18-55 years) | 1                 | 1                | 36.8             | 106                            | 62                              | 78                     | .           | .           |
| CV01HC050  | 50 µg<br>(18-55 years) | 8                 | 8                | 36.7             | 106                            | 59                              | 69                     | .           | .           |
| CV01HC050  | 50 µg<br>(18-55 years) | 15                | 15               | 36.1             | 97                             | 53                              | 62                     | .           | .           |
| CV01HC050  | 50 µg<br>(18-55 years) | 29                | 29               | 36.8             | 104                            | 57                              | 75                     | .           | .           |
| CV01HC050  | 50 µg<br>(18-55 years) | 36                | 36               | 36.7             | 95                             | 54                              | 68                     | .           | .           |
| CV01HC050  | 50 µg<br>(18-55 years) | 43                | 43               | 36.8             | 96                             | 56                              | 70                     | .           | .           |
| CV01HC050  | 50 µg<br>(18-55 years) | 57                | 57               | 37               | 98                             | 59                              | 70                     | .           | .           |
| CV01HC050  | 50 µg<br>(18-55 years) | 119               | 114              | 36.1             | 98                             | 62                              | 72                     | .           | .           |
| CV01HC051  | 50 µg<br>(18-55 years) | -1                | -3               | 37.1             | 129                            | 70                              | 80                     | 56.4        | 162.6       |
| CV01HC051  | 50 µg<br>(18-55 years) | 1                 | 1                | 36.4             | 132                            | 62                              | 71                     | .           | .           |
| CV01HC051  | 50 µg<br>(18-55 years) | 8                 | 8                | 36.8             | 117                            | 73                              | 80                     | .           | .           |
| CV01HC051  | 50 µg<br>(18-55 years) | 15                | 15               | 36.9             | 124                            | 68                              | 72                     | .           | .           |
| CV01HC051  | 50 µg<br>(18-55 years) | 29                | 27               | 36.8             | 125                            | 72                              | 70                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01HC051  | 50 µg<br>(18-55 years) | 36                | 34               | 36.9             | 112                            | 70                              | 81                     | .           | .           |
| CV01HC051  | 50 µg<br>(18-55 years) | 43                | 41               | 36.9             | 108                            | 72                              | 77                     | .           | .           |
| CV01HC051  | 50 µg<br>(18-55 years) | 57                | 55               | 36.4             | 120                            | 76                              | 79                     | .           | .           |
| CV01HC051  | 50 µg<br>(18-55 years) | 119               | 118              | 36.6             | 114                            | 70                              | 65                     | .           | .           |
| CV01HC054  | 50 µg<br>(18-55 years) | -1                | -2               | 36.9             | 109                            | 64                              | 67                     | 64.2        | 180.3       |
| CV01HC054  | 50 µg<br>(18-55 years) | 1                 | 1                | 36.7             | 115                            | 72                              | 79                     | .           | .           |
| CV01HC054  | 50 µg<br>(18-55 years) | 8                 | 8                | 36.9             | 102                            | 61                              | 74                     | .           | .           |
| CV01HC054  | 50 µg<br>(18-55 years) | 15                | 14               | 36.8             | 106                            | 67                              | 72                     | .           | .           |
| CV01HC054  | 50 µg<br>(18-55 years) | 29                | 27               | 36.9             | 109                            | 60                              | 72                     | .           | .           |
| CV01HC054  | 50 µg<br>(18-55 years) | 36                | 34               | 37.1             | 113                            | 58                              | 77                     | .           | .           |
| CV01HC054  | 50 µg<br>(18-55 years) | 43                | 41               | 36.9             | 110                            | 72                              | 77                     | .           | .           |
| CV01HC054  | 50 µg<br>(18-55 years) | 57                | 55               | 36.9             | 110                            | 72                              | 76                     | .           | .           |
| CV01HC054  | 50 µg<br>(18-55 years) | 119               | 118              | 36.9             | 119                            | 75                              | 81                     | .           | .           |
| CV01KP001  | 25 µg<br>(18-55 years) | -1                | -10              | 36.9             | 147 (Mild)                     | 91 (Mild)                       | 75                     | 92.7        | 185.7       |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP001  | 25 µg<br>(18-55 years) | 1                 | 1                | 36.9             | 132                            | 88                              | 77                     | .           | .           |
| CV01KP001  | 25 µg<br>(18-55 years) | 8                 | 8                | 37.3             | 122                            | 80                              | 60                     | .           | .           |
| CV01KP001  | 25 µg<br>(18-55 years) | 15                | 16               | 36.9             | 130                            | 76                              | 88                     | .           | .           |
| CV01KP001  | 25 µg<br>(18-55 years) | 29                | 30               | 36.8             | 142 (Mild)                     | 80                              | 72                     | .           | .           |
| CV01KP001  | 25 µg<br>(18-55 years) | 36                | 38               | 36.9             | 128                            | 82                              | 62                     | .           | .           |
| CV01KP001  | 25 µg<br>(18-55 years) | 43                | 44               | 36.6             | 130                            | 84                              | 64                     | .           | .           |
| CV01KP001  | 25 µg<br>(18-55 years) | 57                | 59               | 36.8             | 120                            | 80                              | 80                     | .           | .           |
| CV01KP001  | 25 µg<br>(18-55 years) | 119               | 114              | 36.9             | 140                            | 78                              | 64                     | .           | .           |
| CV01KP001  | 25 µg<br>(18-55 years) | 209               | 205              | 36.6             | 110                            | 78                              | 66                     | .           | .           |
| CV01KP005  | 25 µg<br>(18-55 years) | -1                | -9               | 36.6             | 106                            | 74                              | 65                     | 56.2        | 158.7       |
| CV01KP005  | 25 µg<br>(18-55 years) | 1                 | 1                | 37.1             | 104                            | 65                              | 72                     | .           | .           |
| CV01KP005  | 25 µg<br>(18-55 years) | 8                 | 8                | 37.2             | 101                            | 64                              | 88                     | .           | .           |
| CV01KP005  | 25 µg<br>(18-55 years) | 15                | 15               | 36.8             | 114                            | 69                              | 99                     | .           | .           |
| CV01KP005  | 25 µg<br>(18-55 years) | 29                | 30               | 37.1             | 102                            | 67                              | 84                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP005  | 25 µg<br>(18-55 years) | 36                | 38               | 37.2             | 113                            | 79                              | 89                     | .           | .           |
| CV01KP005  | 25 µg<br>(18-55 years) | 43                | 44               | 36.9             | 103                            | 58                              | 86                     | .           | .           |
| CV01KP005  | 25 µg<br>(18-55 years) | 57                | 59               | 37               | 111                            | 72                              | 83                     | .           | .           |
| CV01KP005  | 25 µg<br>(18-55 years) | 119               | 113              | 37.1             | 112                            | 73                              | 93                     | .           | .           |
| CV01KP006  | 25 µg<br>(18-55 years) | -1                | -9               | 36.6             | 114                            | 69                              | 56                     | 62.9        | 172.6       |
| CV01KP006  | 25 µg<br>(18-55 years) | 1                 | 1                | 37               | 120                            | 63                              | 56                     | .           | .           |
| CV01KP006  | 25 µg<br>(18-55 years) | 8                 | 8                | 36.7             | 111                            | 65                              | 67                     | .           | .           |
| CV01KP006  | 25 µg<br>(18-55 years) | 15                | 15               | 36.7             | 112                            | 63                              | 65                     | .           | .           |
| CV01KP006  | 25 µg<br>(18-55 years) | 29                | 30               | 37               | 106                            | 56                              | 58                     | .           | .           |
| CV01KP006  | 25 µg<br>(18-55 years) | 36                | 38               | 37.2             | 118                            | 61                              | 57                     | .           | .           |
| CV01KP006  | 25 µg<br>(18-55 years) | 43                | 44               | 36.7             | 108                            | 53                              | 62                     | .           | .           |
| CV01KP006  | 25 µg<br>(18-55 years) | 57                | 59               | 36.6             | 114                            | 64                              | 65                     | .           | .           |
| CV01KP006  | 25 µg<br>(18-55 years) | 119               | 121              | 37.1             | 119                            | 70                              | 79                     | .           | .           |
| CV01KP007  | 25 µg<br>(18-55 years) | -1                | -9               | 36.6             | 105                            | 65                              | 80                     | 57.8        | 164.6       |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP007  | 25 µg<br>(18-55 years)  | 1                 | 1                | 36.4             | 128                            | 61                              | 87                     | .           | .           |
| CV01KP007  | 25 µg<br>(18-55 years)  | 8                 | 8                | 36.4             | 113                            | 57                              | 82                     | .           | .           |
| CV01KP007  | 25 µg<br>(18-55 years)  | 15                | 15               | 36.6             | 103                            | 65                              | 69                     | .           | .           |
| CV01KP007  | 25 µg<br>(18-55 years)  | 29                | 30               | 36.9             | 114                            | 59                              | 77                     | .           | .           |
| CV01KP007  | 25 µg<br>(18-55 years)  | 36                | 38               | 36.4             | 115                            | 52                              | 76                     | .           | .           |
| CV01KP007  | 25 µg<br>(18-55 years)  | 43                | 44               | 37.1             | 109                            | 52                              | 81                     | .           | .           |
| CV01KP007  | 25 µg<br>(18-55 years)  | 57                | 59               | 36.8             | 100                            | 66                              | 78                     | .           | .           |
| CV01KP007  | 25 µg<br>(18-55 years)  | 119               | 113              | 36.4             | 104                            | 52                              | 69                     | .           | .           |
| CV01KP008  | 100 µg<br>(18-55 years) | -1                | -7               | 36.7             | 139                            | 97 (Moderate)                   | 73                     | 83.4        | 162.6       |
| CV01KP008  | 100 µg<br>(18-55 years) | 1                 | 1                | 37.1             | 137                            | 80                              | 94                     | .           | .           |
| CV01KP008  | 100 µg<br>(18-55 years) | 8                 | 7                | 37               | 122                            | 79                              | 64                     | .           | .           |
| CV01KP008  | 100 µg<br>(18-55 years) | 15                | 14               | 37.1             | 131                            | 83                              | 68                     | .           | .           |
| CV01KP008  | 100 µg<br>(18-55 years) | 29                | 29               | 37.1             | 133                            | 76                              | 82                     | .           | .           |
| CV01KP008  | 100 µg<br>(18-55 years) | 36                | 35               | 37               | 127                            | 79                              | 70                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP008  | 100 µg<br>(18-55 years) | 43                | 42               | 36.8             | 125                            | 71                              | 64                     | .           | .           |
| CV01KP008  | 100 µg<br>(18-55 years) | 57                | 59               | 36.6             | 122                            | 84                              | 68                     | .           | .           |
| CV01KP008  | 100 µg<br>(18-55 years) | 119               | 113              | 36.7             | 135                            | 83                              | 68                     | .           | .           |
| CV01KP009  | 100 µg<br>(18-55 years) | -1                | -7               | 36.8             | 103                            | 55                              | 73                     | 54.2        | 163.1       |
| CV01KP009  | 100 µg<br>(18-55 years) | 1                 | 1                | 36.8             | 103                            | 55                              | 70                     | .           | .           |
| CV01KP009  | 100 µg<br>(18-55 years) | 8                 | 7                | 36.9             | 105                            | 52                              | 67                     | .           | .           |
| CV01KP009  | 100 µg<br>(18-55 years) | 15                | 14               | 37               | 101                            | 62                              | 68                     | .           | .           |
| CV01KP009  | 100 µg<br>(18-55 years) | 29                | 29               | 37.1             | 97                             | 54                              | 65                     | .           | .           |
| CV01KP009  | 100 µg<br>(18-55 years) | 36                | 37               | 36.8             | 115                            | 64                              | 68                     | .           | .           |
| CV01KP009  | 100 µg<br>(18-55 years) | 43                | 43               | 36.9             | 96                             | 54                              | 79                     | .           | .           |
| CV01KP009  | 100 µg<br>(18-55 years) | 57                | 59               | 36.9             | 108                            | 56                              | 76                     | .           | .           |
| CV01KP009  | 100 µg<br>(18-55 years) | 119               | 112              | 36.7             | 101                            | 57                              | 67                     | .           | .           |
| CV01KP010  | 25 µg<br>(18-55 years)  | -1                | -14              | 36.5             | 117                            | 61                              | 61                     | 72.2        | 166.1       |
| CV01KP010  | 25 µg<br>(18-55 years)  | 1                 | 1                | 36.9             | 103                            | 61                              | 66                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP010  | 25 µg<br>(18-55 years) | 8                 | 9                | 36.9             | 110                            | 68                              | 60                     | .           | .           |
| CV01KP010  | 25 µg<br>(18-55 years) | 15                | 14               | 36.6             | 108                            | 70                              | 67                     | .           | .           |
| CV01KP010  | 25 µg<br>(18-55 years) | 29                | 29               | 36.4             | 109                            | 71                              | 69                     | .           | .           |
| CV01KP010  | 25 µg<br>(18-55 years) | 36                | 37               | 36.3             | 102                            | 59                              | 63                     | .           | .           |
| CV01KP010  | 25 µg<br>(18-55 years) | 43                | 45               | 36.8             | 105                            | 59                              | 73                     | .           | .           |
| CV01KP010  | 25 µg<br>(18-55 years) | 57                | 56               | 36.8             | 111                            | 72                              | 66                     | .           | .           |
| CV01KP010  | 25 µg<br>(18-55 years) | 119               | 114              | 36.7             | 106                            | 56                              | 77                     | .           | .           |
| CV01KP011  | 25 µg<br>(18-55 years) | -1                | -14              | 36.3             | 121                            | 70                              | 61                     | 107.9       | 182         |
| CV01KP011  | 25 µg<br>(18-55 years) | 1                 | 1                | 36.8             | 128                            | 73                              | 89                     | .           | .           |
| CV01KP011  | 25 µg<br>(18-55 years) | 8                 | 9                | 36.9             | 112                            | 74                              | 96                     | .           | .           |
| CV01KP011  | 25 µg<br>(18-55 years) | 15                | 14               | 36.7             | 116                            | 68                              | 69                     | .           | .           |
| CV01KP011  | 25 µg<br>(18-55 years) | 29                | 29               | 36.8             | 150 (Mild)                     | 69                              | 81                     | .           | .           |
| CV01KP011  | 25 µg<br>(18-55 years) | 36                | 37               | 36.8             | 112                            | 64                              | 75                     | .           | .           |
| CV01KP011  | 25 µg<br>(18-55 years) | 43                | 45               | 36.7             | 116                            | 64                              | 72                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP011  | 25 µg<br>(18-55 years)  | 57                | 56               | 36.8             | 115                            | 68                              | 81                     | .           | .           |
| CV01KP011  | 25 µg<br>(18-55 years)  | 119               | 113              | 36.8             | 121                            | 76                              | 70                     | .           | .           |
| CV01KP012  | 100 µg<br>(18-55 years) | -1                | -6               | 36.4             | 139                            | 66                              | 55                     | 81.6        | 169.2       |
| CV01KP012  | 100 µg<br>(18-55 years) | 1                 | 1                | 37.2             | 138                            | 71                              | 72                     | .           | .           |
| CV01KP012  | 100 µg<br>(18-55 years) | 8                 | 7                | 37.1             | 130                            | 65                              | 68                     | .           | .           |
| CV01KP012  | 100 µg<br>(18-55 years) | 15                | 14               | 37.1             | 118                            | 60                              | 69                     | .           | .           |
| CV01KP012  | 100 µg<br>(18-55 years) | 29                | 29               | 36.9             | 120                            | 61                              | 70                     | .           | .           |
| CV01KP012  | 100 µg<br>(18-55 years) | 36                | 37               | 37.1             | 117                            | 56                              | 68                     | .           | .           |
| CV01KP012  | 100 µg<br>(18-55 years) | 43                | 43               | 37.1             | 114                            | 72                              | 80                     | .           | .           |
| CV01KP012  | 100 µg<br>(18-55 years) | 57                | 58               | 37.2             | 109                            | 52                              | 73                     | .           | .           |
| CV01KP012  | 100 µg<br>(18-55 years) | 119               | 112              | 37.1             | 117                            | 60                              | 92                     | .           | .           |
| CV01KP012  | 100 µg<br>(18-55 years) | 209               | 204              | 37.4             | 133                            | 74                              | 66                     | .           | .           |
| CV01KP014  | 100 µg<br>(18-55 years) | -1                | -6               | 36.8             | 114                            | 69                              | 84                     | 72.5        | 166.6       |
| CV01KP014  | 100 µg<br>(18-55 years) | 1                 | 1                | 36.6             | 116                            | 67                              | 87                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP014  | 100 µg<br>(18-55 years) | 8                 | 7                | 36.7             | 112                            | 63                              | 93                     | .           | .           |
| CV01KP014  | 100 µg<br>(18-55 years) | 15                | 14               | 37               | 114                            | 67                              | 88                     | .           | .           |
| CV01KP014  | 100 µg<br>(18-55 years) | 29                | 29               | 36.9             | 94                             | 50                              | 81                     | .           | .           |
| CV01KP014  | 100 µg<br>(18-55 years) | 36                | 37               | 37.4             | 119                            | 55                              | 94                     | .           | .           |
| CV01KP014  | 100 µg<br>(18-55 years) | 43                | 43               | 37               | 113                            | 61                              | 97                     | .           | .           |
| CV01KP014  | 100 µg<br>(18-55 years) | 57                | 58               | 37.3             | 96                             | 52                              | 73                     | .           | .           |
| CV01KP014  | 100 µg<br>(18-55 years) | 119               | 112              | 37.4             | 105                            | 56                              | 96                     | .           | .           |
| CV01KP014  | 100 µg<br>(18-55 years) | 209               | 204              | 36.9             | 124                            | 65                              | 83                     | .           | .           |
| CV01KP015  | 25 µg<br>(18-55 years)  | -1                | -13              | 36.5             | 110                            | 70                              | 63                     | 76.6        | 173.7       |
| CV01KP015  | 25 µg<br>(18-55 years)  | 1                 | 1                | 37.2             | 101                            | 62                              | 79                     | .           | .           |
| CV01KP015  | 25 µg<br>(18-55 years)  | 8                 | 9                | 37               | 105                            | 65                              | 66                     | .           | .           |
| CV01KP015  | 25 µg<br>(18-55 years)  | 15                | 14               | 36.8             | 110                            | 72                              | 81                     | .           | .           |
| CV01KP015  | 25 µg<br>(18-55 years)  | 29                | 29               | 36.8             | 107                            | 64                              | 68                     | .           | .           |
| CV01KP015  | 25 µg<br>(18-55 years)  | 36                | 37               | 36.5             | 106                            | 62                              | 67                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP015  | 25 µg<br>(18-55 years) | 43                | 45               | 37               | 115                            | 68                              | 73                     | .           | .           |
| CV01KP015  | 25 µg<br>(18-55 years) | 57                | 58               | 36.8             | 102                            | 61                              | 81                     | .           | .           |
| CV01KP015  | 25 µg<br>(18-55 years) | 119               | 112              | 36.4             | 121                            | 67                              | 61                     | .           | .           |
| CV01KP018  | 25 µg<br>(18-55 years) | -1                | -12              | 36.5             | 115                            | 70                              | 64                     | 88.3        | 182.1       |
| CV01KP018  | 25 µg<br>(18-55 years) | 1                 | 1                | 36.7             | 114                            | 65                              | 57                     | .           | .           |
| CV01KP018  | 25 µg<br>(18-55 years) | 15                | 17               | 36.7             | 133                            | 76                              | 62                     | .           | .           |
| CV01KP018  | 25 µg<br>(18-55 years) | 29                | 29               | 36.7             | 125                            | 69                              | 56                     | .           | .           |
| CV01KP018  | 25 µg<br>(18-55 years) | 36                | 37               | 36.6             | 114                            | 65                              | 55                     | .           | .           |
| CV01KP018  | 25 µg<br>(18-55 years) | 43                | 45               | 36.9             | 126                            | 61                              | 55                     | .           | .           |
| CV01KP018  | 25 µg<br>(18-55 years) | 57                | 57               | 36.8             | 118                            | 67                              | 65                     | .           | .           |
| CV01KP018  | 25 µg<br>(18-55 years) | 119               | 114              | 36.9             | 114                            | 60                              | 67                     | .           | .           |
| CV01KP023  | 25 µg<br>(18-55 years) | -1                | -11              | 36.9             | 115                            | 59                              | 62                     | 72.8        | 182.9       |
| CV01KP023  | 25 µg<br>(18-55 years) | 1                 | 1                | 36.8             | 110                            | 58                              | 60                     | .           | .           |
| CV01KP023  | 25 µg<br>(18-55 years) | 8                 | 9                | 36.6             | 113                            | 73                              | 73                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP023  | 25 µg<br>(18-55 years) | 15                | 14               | 36.9             | 104                            | 60                              | 68                     | .           | .           |
| CV01KP023  | 25 µg<br>(18-55 years) | 29                | 29               | 36.9             | 115                            | 57                              | 72                     | .           | .           |
| CV01KP023  | 25 µg<br>(18-55 years) | 36                | 37               | 36.4             | 116                            | 53                              | 82                     | .           | .           |
| CV01KP023  | 25 µg<br>(18-55 years) | 43                | 45               | 36.4             | 117                            | 68                              | 73                     | .           | .           |
| CV01KP023  | 25 µg<br>(18-55 years) | 57                | 57               | 36.8             | 114                            | 65                              | 70                     | .           | .           |
| CV01KP023  | 25 µg<br>(18-55 years) | 119               | 113              | 36.5             | 119                            | 69                              | 70                     | .           | .           |
| CV01KP024  | 25 µg<br>(18-55 years) | -1                | -11              | 36.8             | 107                            | 72                              | 77                     | 91.5        | 174.2       |
| CV01KP024  | 25 µg<br>(18-55 years) | 1                 | 1                | 36.7             | 111                            | 72                              | 81                     | .           | .           |
| CV01KP024  | 25 µg<br>(18-55 years) | 8                 | 9                | 36.8             | 121                            | 85                              | 95                     | .           | .           |
| CV01KP024  | 25 µg<br>(18-55 years) | 15                | 14               | 36.7             | 117                            | 71                              | 75                     | .           | .           |
| CV01KP024  | 25 µg<br>(18-55 years) | 29                | 29               | 36.7             | 115                            | 71                              | 73                     | .           | .           |
| CV01KP024  | 25 µg<br>(18-55 years) | 36                | 36               | 36.6             | 118                            | 73                              | 84                     | .           | .           |
| CV01KP024  | 25 µg<br>(18-55 years) | 43                | 45               | 36.8             | 125                            | 76                              | 98                     | .           | .           |
| CV01KP024  | 25 µg<br>(18-55 years) | 57                | 56               | 36.8             | 114                            | 71                              | 93                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP024  | 25 µg<br>(18-55 years) | 119               | 113              | 36.9             | 120                            | 73                              | 90                     | .           | .           |
| CV01KP026  | 25 µg<br>(18-55 years) | -1                | -11              | 36.9             | 106                            | 67                              | 84                     | 65.9        | 174.5       |
| CV01KP026  | 25 µg<br>(18-55 years) | 1                 | 1                | 36.8             | 124                            | 80                              | 82                     | .           | .           |
| CV01KP026  | 25 µg<br>(18-55 years) | 8                 | 9                | 36.8             | 107                            | 70                              | 97                     | .           | .           |
| CV01KP026  | 25 µg<br>(18-55 years) | 15                | 14               | 37.6             | 110                            | 67                              | 80                     | .           | .           |
| CV01KP026  | 25 µg<br>(18-55 years) | 29                | 29               | 36.7             | 104                            | 64                              | 78                     | .           | .           |
| CV01KP026  | 25 µg<br>(18-55 years) | 36                | 37               | 37.1             | 111                            | 71                              | 79                     | .           | .           |
| CV01KP026  | 25 µg<br>(18-55 years) | 43                | 45               | 36.8             | 100                            | 58                              | 91                     | .           | .           |
| CV01KP026  | 25 µg<br>(18-55 years) | 57                | 56               | 37.1             | 111                            | 71                              | 93                     | .           | .           |
| CV01KP026  | 25 µg<br>(18-55 years) | 119               | 113              | 37               | 101                            | 67                              | 81                     | .           | .           |
| CV01KP027  | 25 µg<br>(18-55 years) | -1                | -10              | 37.3             | 129                            | 79                              | 75                     | 71.5        | 177.4       |
| CV01KP027  | 25 µg<br>(18-55 years) | 1                 | 1                | 36.7             | 131                            | 79                              | 78                     | .           | .           |
| CV01KP027  | 25 µg<br>(18-55 years) | 8                 | 9                | 36.6             | 123                            | 76                              | 77                     | .           | .           |
| CV01KP027  | 25 µg<br>(18-55 years) | 15                | 14               | 36.7             | 115                            | 72                              | 74                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP027  | 25 µg<br>(18-55 years) | 29                | 29               | 36.8             | 108                            | 62                              | 83                     | .           | .           |
| CV01KP027  | 25 µg<br>(18-55 years) | 36                | 37               | 36.7             | 106                            | 59                              | 81                     | .           | .           |
| CV01KP027  | 25 µg<br>(18-55 years) | 43                | 45               | 36.6             | 117                            | 72                              | 83                     | .           | .           |
| CV01KP027  | 25 µg<br>(18-55 years) | 57                | 56               | 36.8             | 113                            | 68                              | 76                     | .           | .           |
| CV01KP027  | 25 µg<br>(18-55 years) | 119               | 114              | 36.7             | 132                            | 81                              | 77                     | .           | .           |
| CV01KP028  | 25 µg<br>(18-55 years) | -1                | -10              | 37.2             | 105                            | 64                              | 72                     | 69.2        | 167.4       |
| CV01KP028  | 25 µg<br>(18-55 years) | 1                 | 1                | 36.8             | 104                            | 55                              | 72                     | .           | .           |
| CV01KP028  | 25 µg<br>(18-55 years) | 8                 | 9                | 36.7             | 110                            | 65                              | 85                     | .           | .           |
| CV01KP028  | 25 µg<br>(18-55 years) | 15                | 14               | 37.1             | 108                            | 66                              | 80                     | .           | .           |
| CV01KP028  | 25 µg<br>(18-55 years) | 29                | 29               | 36.8             | 99                             | 58                              | 70                     | .           | .           |
| CV01KP028  | 25 µg<br>(18-55 years) | 36                | 37               | 36.7             | 110                            | 60                              | 78                     | .           | .           |
| CV01KP028  | 25 µg<br>(18-55 years) | 43                | 45               | 36.8             | 110                            | 60                              | 84                     | .           | .           |
| CV01KP028  | 25 µg<br>(18-55 years) | 57                | 58               | 36.6             | 118                            | 57                              | 79                     | .           | .           |
| CV01KP028  | 25 µg<br>(18-55 years) | 119               | 113              | 36.9             | 109                            | 55                              | 73                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP030  | 250 µg<br>(18-55 years) | -1                | -25              | 37.2             | 142 (Mild)                     | 82                              | 56                     | 76.7        | 185.7       |
| CV01KP030  | 250 µg<br>(18-55 years) | 1                 | 1                | 36.7             | 133                            | 69                              | 90                     | .           | .           |
| CV01KP030  | 250 µg<br>(18-55 years) | 8                 | 8                | 36.7             | 132                            | 60                              | 63                     | .           | .           |
| CV01KP030  | 250 µg<br>(18-55 years) | 15                | 15               | 37               | 128                            | 68                              | 62                     | .           | .           |
| CV01KP030  | 250 µg<br>(18-55 years) | 29                | 28               | 36.4             | 125                            | 75                              | 63                     | .           | .           |
| CV01KP030  | 250 µg<br>(18-55 years) | 36                | 35               | 36.8             | 120                            | 64                              | 65                     | .           | .           |
| CV01KP030  | 250 µg<br>(18-55 years) | 43                | 43               | 36.3             | 122                            | 71                              | 67                     | .           | .           |
| CV01KP030  | 250 µg<br>(18-55 years) | 57                | 56               | 36.9             | 116                            | 62                              | 57                     | .           | .           |
| CV01KP030  | 250 µg<br>(18-55 years) | 119               | 112              | 36.5             | 119                            | 67                              | 72                     | .           | .           |
| CV01KP031  | 25 µg<br>(18-55 years)  | -1                | -10              | 36.9             | 131                            | 72                              | 72                     | 68.8        | 179.5       |
| CV01KP031  | 25 µg<br>(18-55 years)  | 1                 | 1                | 36.8             | 124                            | 69                              | 69                     | .           | .           |
| CV01KP031  | 25 µg<br>(18-55 years)  | 8                 | 9                | 36.6             | 116                            | 70                              | 79                     | .           | .           |
| CV01KP031  | 25 µg<br>(18-55 years)  | 15                | 14               | 37               | 104                            | 58                              | 71                     | .           | .           |
| CV01KP031  | 25 µg<br>(18-55 years)  | 29                | 29               | 37.1             | 104                            | 58                              | 78                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP031  | 25 µg<br>(18-55 years)  | 36                | 37               | 36.8             | 123                            | 69                              | 92                     | .           | .           |
| CV01KP031  | 25 µg<br>(18-55 years)  | 43                | 45               | 36.6             | 120                            | 79                              | 86                     | .           | .           |
| CV01KP031  | 25 µg<br>(18-55 years)  | 57                | 56               | 36.7             | 110                            | 73                              | 80                     | .           | .           |
| CV01KP031  | 25 µg<br>(18-55 years)  | 119               | 113              | 36.5             | 110                            | 65                              | 77                     | .           | .           |
| CV01KP032  | 25 µg<br>(18-55 years)  | -1                | -7               | 36.6             | 132                            | 74                              | 98                     | 92.3        | 194.1       |
| CV01KP032  | 25 µg<br>(18-55 years)  | 1                 | 1                | 36.4             | 129                            | 73                              | 69                     | .           | .           |
| CV01KP032  | 25 µg<br>(18-55 years)  | 8                 | 9                | 36.6             | 122                            | 67                              | 71                     | .           | .           |
| CV01KP032  | 25 µg<br>(18-55 years)  | 15                | 14               | 36.9             | 109                            | 64                              | 66                     | .           | .           |
| CV01KP032  | 25 µg<br>(18-55 years)  | 29                | 29               | 36.6             | 116                            | 62                              | 75                     | .           | .           |
| CV01KP032  | 25 µg<br>(18-55 years)  | 36                | 37               | 36.8             | 119                            | 55                              | 79                     | .           | .           |
| CV01KP032  | 25 µg<br>(18-55 years)  | 43                | 45               | 36.5             | 114                            | 68                              | 72                     | .           | .           |
| CV01KP032  | 25 µg<br>(18-55 years)  | 57                | 57               | 37.1             | 121                            | 59                              | 79                     | .           | .           |
| CV01KP032  | 25 µg<br>(18-55 years)  | 119               | 114              | 36.4             | 128                            | 62                              | 73                     | .           | .           |
| CV01KP033  | 250 µg<br>(18-55 years) | -1                | -21              | 36.9             | 107                            | 56                              | 72                     | 53          | 161         |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP033  | 250 µg<br>(18-55 years) | 1                 | 1                | 36.7             | 116                            | 72                              | 70                     | .           | .           |
| CV01KP033  | 250 µg<br>(18-55 years) | 8                 | 8                | 36.8             | 111                            | 75                              | 70                     | .           | .           |
| CV01KP033  | 250 µg<br>(18-55 years) | 15                | 16               | 36.6             | 116                            | 72                              | 77                     | .           | .           |
| CV01KP033  | 250 µg<br>(18-55 years) | 29                | 28               | 36.5             | 117                            | 76                              | 68                     | .           | .           |
| CV01KP033  | 250 µg<br>(18-55 years) | 36                | 35               | 36.7             | 110                            | 69                              | 82                     | .           | .           |
| CV01KP033  | 250 µg<br>(18-55 years) | 43                | 43               | 36.6             | 122                            | 68                              | 95                     | .           | .           |
| CV01KP033  | 250 µg<br>(18-55 years) | 57                | 56               | 36.9             | 112                            | 61                              | 70                     | .           | .           |
| CV01KP033  | 250 µg<br>(18-55 years) | 119               | 112              | 36.8             | 118                            | 69                              | 77                     | .           | .           |
| CV01KP036  | 250 µg<br>(18-55 years) | -1                | -25              | 37.2             | 136                            | 96 (Moderate)                   | 87                     | 81.1        | 173.2       |
| CV01KP036  | 250 µg<br>(18-55 years) | 1                 | 1                | 37               | 133                            | 85                              | 87                     | .           | .           |
| CV01KP036  | 250 µg<br>(18-55 years) | 8                 | 8                | 36.9             | 138                            | 91 (Mild)                       | 56                     | .           | .           |
| CV01KP036  | 250 µg<br>(18-55 years) | 15                | 15               | 36.9             | 138                            | 83                              | 64                     | .           | .           |
| CV01KP036  | 250 µg<br>(18-55 years) | 29                | 29               | 37.7             | 137                            | 83                              | 84                     | .           | .           |
| CV01KP036  | 250 µg<br>(18-55 years) | 36                | 36               | 37.2             | 130                            | 84                              | 75                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP036  | 250 µg<br>(18-55 years) | 43                | 44               | 37.1             | 133                            | 87                              | 91                     | .           | .           |
| CV01KP036  | 250 µg<br>(18-55 years) | 57                | 59               | 37               | 126                            | 74                              | 94                     | .           | .           |
| CV01KP036  | 250 µg<br>(18-55 years) | 119               | 113              | 37.1             | 130                            | 86                              | 82                     | .           | .           |
| CV01KP037  | 250 µg<br>(18-55 years) | -1                | -20              | 37               | 122                            | 62                              | 90                     | 53.2        | 159.8       |
| CV01KP037  | 250 µg<br>(18-55 years) | 1                 | 1                | 37.4             | 114                            | 62                              | 88                     | .           | .           |
| CV01KP037  | 250 µg<br>(18-55 years) | 8                 | 8                | 36.9             | 118                            | 72                              | 88                     | .           | .           |
| CV01KP037  | 250 µg<br>(18-55 years) | 15                | 16               | 36.5             | 131                            | 72                              | 89                     | .           | .           |
| CV01KP037  | 250 µg<br>(18-55 years) | 36                | 35               | 36.7             | 111                            | 55                              | 84                     | .           | .           |
| CV01KP037  | 250 µg<br>(18-55 years) | 43                | 43               | 36.7             | 122                            | 72                              | 82                     | .           | .           |
| CV01KP037  | 250 µg<br>(18-55 years) | 57                | 56               | 37.2             | 113                            | 59                              | 81                     | .           | .           |
| CV01KP037  | 250 µg<br>(18-55 years) | 119               | 112              | 36.9             | 108                            | 66                              | 86                     | .           | .           |
| CV01KP040  | 250 µg<br>(18-55 years) | -1                | -19              | 37               | 127                            | 66                              | 77                     | 75.6        | 176.2       |
| CV01KP040  | 250 µg<br>(18-55 years) | 1                 | 1                | 37.4             | 120                            | 69                              | 99                     | .           | .           |
| CV01KP040  | 250 µg<br>(18-55 years) | 8                 | 8                | 36.8             | 131                            | 75                              | 90                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP040  | 250 µg<br>(18-55 years) | 15                | 16               | 37.1             | 116                            | 67                              | 86                     | .           | .           |
| CV01KP040  | 250 µg<br>(18-55 years) | 29                | 28               | 37.1             | 130                            | 65                              | 83                     | .           | .           |
| CV01KP040  | 250 µg<br>(18-55 years) | 36                | 35               | 37.1             | 129                            | 67                              | 74                     | .           | .           |
| CV01KP040  | 250 µg<br>(18-55 years) | 43                | 43               | 37.1             | 123                            | 75                              | 71                     | .           | .           |
| CV01KP040  | 250 µg<br>(18-55 years) | 57                | 56               | 37               | 119                            | 61                              | 88                     | .           | .           |
| CV01KP040  | 250 µg<br>(18-55 years) | 119               | 112              | 36.4             | 115                            | 64                              | 72                     | .           | .           |
| CV01KP041  | 250 µg<br>(18-55 years) | -1                | -24              | 36.9             | 142 (Mild)                     | 85                              | 53 (Mild)              | 80.1        | 167         |
| CV01KP041  | 250 µg<br>(18-55 years) | 1                 | 1                | 37               | 124                            | 68                              | 75                     | .           | .           |
| CV01KP041  | 250 µg<br>(18-55 years) | 8                 | 8                | 36.9             | 131                            | 75                              | 74                     | .           | .           |
| CV01KP041  | 250 µg<br>(18-55 years) | 15                | 15               | 36.9             | 109                            | 71                              | 62                     | .           | .           |
| CV01KP041  | 250 µg<br>(18-55 years) | 29                | 29               | 37.1             | 126                            | 73                              | 62                     | .           | .           |
| CV01KP041  | 250 µg<br>(18-55 years) | 36                | 37               | 37.1             | 137                            | 81                              | 65                     | .           | .           |
| CV01KP041  | 250 µg<br>(18-55 years) | 43                | 44               | 36.6             | 120                            | 80                              | 59                     | .           | .           |
| CV01KP041  | 250 µg<br>(18-55 years) | 57                | 59               | 36.6             | 120                            | 64                              | 60                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP041  | 250 µg<br>(18-55 years) | 119               | 113              | 37.3             | 132                            | 83                              | 69                     | .           | .           |
| CV01KP048  | 250 µg<br>(18-55 years) | -1                | -23              | 36.7             | 136                            | 82                              | 71                     | 83.9        | 179.3       |
| CV01KP048  | 250 µg<br>(18-55 years) | 1                 | 1                | 36.7             | 139                            | 86                              | 72                     | .           | .           |
| CV01KP048  | 250 µg<br>(18-55 years) | 8                 | 8                | 37.1             | 139                            | 82                              | 69                     | .           | .           |
| CV01KP048  | 250 µg<br>(18-55 years) | 15                | 15               | 36.9             | 131                            | 74                              | 71                     | .           | .           |
| CV01KP048  | 250 µg<br>(18-55 years) | 29                | 29               | 36.9             | 118                            | 66                              | 77                     | .           | .           |
| CV01KP048  | 250 µg<br>(18-55 years) | 36                | 37               | 37.3             | 124                            | 76                              | 71                     | .           | .           |
| CV01KP048  | 250 µg<br>(18-55 years) | 43                | 44               | 36.9             | 134                            | 76                              | 90                     | .           | .           |
| CV01KP048  | 250 µg<br>(18-55 years) | 57                | 59               | 36.9             | 138                            | 81                              | 75                     | .           | .           |
| CV01KP048  | 250 µg<br>(18-55 years) | 119               | 121              | 37.1             | 136                            | 80                              | 75                     | .           | .           |
| CV01KP049  | 250 µg<br>(18-55 years) | -1                | -23              | 36.4             | 102                            | 61                              | 65                     | 52.1        | 152.7       |
| CV01KP049  | 250 µg<br>(18-55 years) | 1                 | 1                | 36.7             | 98                             | 54                              | 63                     | .           | .           |
| CV01KP049  | 250 µg<br>(18-55 years) | 8                 | 8                | 36.9             | 94                             | 52                              | 67                     | .           | .           |
| CV01KP049  | 250 µg<br>(18-55 years) | 15                | 15               | 36.4             | 98                             | 53                              | 52 (Mild)              | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group       | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP049  | 250 µg<br>(18-55 years) | 29                | 29               | 36.7             | 85 (Mild)                      | 49                              | 55                     | .           | .           |
| CV01KP049  | 250 µg<br>(18-55 years) | 36                | 37               | 36.5             | 85 (Mild)                      | 49                              | 61                     | .           | .           |
| CV01KP049  | 250 µg<br>(18-55 years) | 43                | 44               | 36.9             | 92                             | 50                              | 53 (Mild)              | .           | .           |
| CV01KP049  | 250 µg<br>(18-55 years) | 57                | 59               | 36.8             | 101                            | 56                              | 57                     | .           | .           |
| CV01KP049  | 250 µg<br>(18-55 years) | 119               | 113              | 36.4             | 94                             | 54                              | 48 (Moderate)          | .           | .           |
| CV01KP053  | 250 µg<br>(18-55 years) | -1                | -20              | 36.9             | 114                            | 55                              | 71                     | 55.1        | 157.7       |
| CV01KP053  | 250 µg<br>(18-55 years) | 1                 | 1                | 36.7             | 107                            | 63                              | 68                     | .           | .           |
| CV01KP053  | 250 µg<br>(18-55 years) | 8                 | 8                | 36.6             | 114                            | 65                              | 66                     | .           | .           |
| CV01KP053  | 250 µg<br>(18-55 years) | 15                | 15               | 36.9             | 113                            | 65                              | 83                     | .           | .           |
| CV01KP053  | 250 µg<br>(18-55 years) | 29                | 29               | 36.8             | 116                            | 61                              | 77                     | .           | .           |
| CV01KP053  | 250 µg<br>(18-55 years) | 36                | 37               | 37.1             | 105                            | 59                              | 75                     | .           | .           |
| CV01KP053  | 250 µg<br>(18-55 years) | 43                | 44               | 37.1             | 118                            | 69                              | 94                     | .           | .           |
| CV01KP053  | 250 µg<br>(18-55 years) | 57                | 59               | 37.2             | 115                            | 67                              | 91                     | .           | .           |
| CV01KP053  | 250 µg<br>(18-55 years) | 119               | 121              | 36.7             | 110                            | 71                              | 80                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group    | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|----------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP059  | 25 µg<br>(≥71 years) | -1                | -16              | 36.7             | 109                            | 69                              | 76                     | 87.6        | 173.2       |
| CV01KP059  | 25 µg<br>(≥71 years) | 1                 | 1                | 36.7             | 110                            | 68                              | 81                     | .           | .           |
| CV01KP059  | 25 µg<br>(≥71 years) | 8                 | 9                | 36.7             | 112                            | 78                              | 72                     | .           | .           |
| CV01KP059  | 25 µg<br>(≥71 years) | 15                | 15               | 36.5             | 120                            | 78                              | 65                     | .           | .           |
| CV01KP059  | 25 µg<br>(≥71 years) | 29                | 29               | 36.7             | 101                            | 65                              | 68                     | .           | .           |
| CV01KP059  | 25 µg<br>(≥71 years) | 36                | 37               | 36.7             | 119                            | 75                              | 66                     | .           | .           |
| CV01KP059  | 25 µg<br>(≥71 years) | 43                | 44               | 36.6             | 112                            | 66                              | 69                     | .           | .           |
| CV01KP059  | 25 µg<br>(≥71 years) | 57                | 57               | 36.6             | 123                            | 78                              | 70                     | .           | .           |
| CV01KP059  | 25 µg<br>(≥71 years) | 119               | 120              | 37.1             | 115                            | 73                              | 66                     | .           | .           |
| CV01KP060  | 25 µg<br>(≥71 years) | -1                | -16              | 36.9             | 131                            | 60                              | 58                     | 47.4        | 153.9       |
| CV01KP060  | 25 µg<br>(≥71 years) | 1                 | 1                | 36.3             | 145 (Mild)                     | 70                              | 57                     | .           | .           |
| CV01KP060  | 25 µg<br>(≥71 years) | 8                 | 9                | 36.6             | 149 (Mild)                     | 68                              | 53 (Mild)              | .           | .           |
| CV01KP060  | 25 µg<br>(≥71 years) | 15                | 16               | 36.7             | 140                            | 70                              | 58                     | .           | .           |
| CV01KP060  | 25 µg<br>(≥71 years) | 29                | 29               | 36.8             | 135                            | 60                              | 58                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group    | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|----------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP060  | 25 µg<br>(≥71 years) | 36                | 37               | 36.7             | 141 (Mild)                     | 64                              | 55                     | .           | .           |
| CV01KP060  | 25 µg<br>(≥71 years) | 43                | 44               | 36.6             | 138                            | 63                              | 53 (Mild)              | .           | .           |
| CV01KP060  | 25 µg<br>(≥71 years) | 57                | 57               | 36.6             | 132                            | 60                              | 55                     | .           | .           |
| CV01KP060  | 25 µg<br>(≥71 years) | 119               | 113              | 37.2             | 128                            | 74                              | 71                     | .           | .           |
| CV01KP061  | 25 µg<br>(≥71 years) | -1                | -16              | 37.1             | 122                            | 77                              | 71                     | 84          | 179         |
| CV01KP061  | 25 µg<br>(≥71 years) | 1                 | 1                | 36.6             | 128                            | 77                              | 74                     | .           | .           |
| CV01KP061  | 25 µg<br>(≥71 years) | 8                 | 9                | 36.8             | 112                            | 72                              | 73                     | .           | .           |
| CV01KP061  | 25 µg<br>(≥71 years) | 15                | 15               | 36.7             | 113                            | 68                              | 71                     | .           | .           |
| CV01KP061  | 25 µg<br>(≥71 years) | 29                | 29               | 36.7             | 108                            | 65                              | 72                     | .           | .           |
| CV01KP061  | 25 µg<br>(≥71 years) | 36                | 37               | 36.7             | 111                            | 73                              | 68                     | .           | .           |
| CV01KP061  | 25 µg<br>(≥71 years) | 43                | 44               | 36.8             | 111                            | 67                              | 71                     | .           | .           |
| CV01KP061  | 25 µg<br>(≥71 years) | 57                | 57               | 36.6             | 120                            | 70                              | 78                     | .           | .           |
| CV01KP061  | 25 µg<br>(≥71 years) | 119               | 113              | 36.7             | 111                            | 75                              | 74                     | .           | .           |
| CV01KP062  | 25 µg<br>(≥71 years) | -1                | -16              | 37.1             | 143 (Mild)                     | 66                              | 75                     | 62.5        | 171.7       |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group    | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|----------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP062  | 25 µg<br>(≥71 years) | 1                 | 1                | 36.8             | 141 (Mild)                     | 76                              | 68                     | .           | .           |
| CV01KP062  | 25 µg<br>(≥71 years) | 8                 | 9                | 37.1             | 129                            | 68                              | 70                     | .           | .           |
| CV01KP062  | 25 µg<br>(≥71 years) | 15                | 15               | 36.7             | 140                            | 76                              | 67                     | .           | .           |
| CV01KP062  | 25 µg<br>(≥71 years) | 29                | 29               | 37.1             | 130                            | 71                              | 72                     | .           | .           |
| CV01KP062  | 25 µg<br>(≥71 years) | 36                | 37               | 36.8             | 132                            | 76                              | 85                     | .           | .           |
| CV01KP062  | 25 µg<br>(≥71 years) | 43                | 44               | 37.1             | 148 (Mild)                     | 84                              | 69                     | .           | .           |
| CV01KP062  | 25 µg<br>(≥71 years) | 57                | 57               | 36.4             | 126                            | 80                              | 68                     | .           | .           |
| CV01KP062  | 25 µg<br>(≥71 years) | 119               | 113              | 35.7             | 132                            | 78                              | 73                     | .           | .           |
| CV01KP063  | 25 µg<br>(≥71 years) | -1                | -13              | 37.1             | 112                            | 73                              | 74                     | 83.5        | 174.9       |
| CV01KP063  | 25 µg<br>(≥71 years) | 1                 | 1                | 36.9             | 136                            | 79                              | 72                     | .           | .           |
| CV01KP063  | 25 µg<br>(≥71 years) | 8                 | 9                | 37.1             | 130                            | 84                              | 80                     | .           | .           |
| CV01KP063  | 25 µg<br>(≥71 years) | 15                | 16               | 36.9             | 134                            | 75                              | 78                     | .           | .           |
| CV01KP063  | 25 µg<br>(≥71 years) | 29                | 29               | 37.3             | 122                            | 80                              | 76                     | .           | .           |
| CV01KP063  | 25 µg<br>(≥71 years) | 36                | 37               | 37               | 125                            | 73                              | 73                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group     | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-----------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP063  | 25 µg<br>(≥71 years)  | 43                | 44               | 37.1             | 119                            | 68                              | 76                     | .           | .           |
| CV01KP063  | 25 µg<br>(≥71 years)  | 57                | 57               | 37               | 121                            | 74                              | 71                     | .           | .           |
| CV01KP063  | 25 µg<br>(≥71 years)  | 119               | 113              | 35.7             | 115                            | 64                              | 71                     | .           | .           |
| CV01KP064  | 100 µg<br>(≥71 years) | -1                | -21              | 36.4             | 121                            | 69                              | 55                     | 83.7        | 169.1       |
| CV01KP064  | 100 µg<br>(≥71 years) | 1                 | 1                | 36.8             | 109                            | 57                              | 62                     | .           | .           |
| CV01KP064  | 100 µg<br>(≥71 years) | 8                 | 9                | 36.6             | 115                            | 55                              | 62                     | .           | .           |
| CV01KP064  | 100 µg<br>(≥71 years) | 15                | 16               | 36.9             | 121                            | 57                              | 56                     | .           | .           |
| CV01KP064  | 100 µg<br>(≥71 years) | 29                | 28               | 36.7             | 121                            | 57                              | 57                     | .           | .           |
| CV01KP064  | 100 µg<br>(≥71 years) | 36                | 35               | 36.7             | 128                            | 61                              | 55                     | .           | .           |
| CV01KP064  | 100 µg<br>(≥71 years) | 43                | 42               | 36.7             | 144 (Mild)                     | 69                              | 50 (Mild)              | .           | .           |
| CV01KP064  | 100 µg<br>(≥71 years) | 57                | 56               | 36.9             | 134                            | 72                              | 56                     | .           | .           |
| CV01KP064  | 100 µg<br>(≥71 years) | 119               | 122              | 36               | 136                            | 69                              | 82                     | .           | .           |
| CV01KP065  | 25 µg<br>(≥71 years)  | -1                | -13              | 36.9             | 126                            | 84                              | 77                     | 78.3        | 171.1       |
| CV01KP065  | 25 µg<br>(≥71 years)  | 1                 | 1                | 36.6             | 148 (Mild)                     | 92 (Mild)                       | 62                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group    | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|----------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP065  | 25 µg<br>(≥71 years) | 8                 | 9                | 36.9             | 128                            | 87                              | 89                     | .           | .           |
| CV01KP065  | 25 µg<br>(≥71 years) | 15                | 16               | 36.7             | 136                            | 85                              | 94                     | .           | .           |
| CV01KP065  | 25 µg<br>(≥71 years) | 29                | 29               | 36.9             | 139                            | 90                              | 88                     | .           | .           |
| CV01KP065  | 25 µg<br>(≥71 years) | 36                | 37               | 37               | 106                            | 61                              | 100                    | .           | .           |
| CV01KP065  | 25 µg<br>(≥71 years) | 43                | 44               | 36.8             | 128                            | 80                              | 65                     | .           | .           |
| CV01KP065  | 25 µg<br>(≥71 years) | 57                | 57               | 36.9             | 132                            | 82                              | 100                    | .           | .           |
| CV01KP065  | 25 µg<br>(≥71 years) | 119               | 113              | 36.9             | 139                            | 89                              | 85                     | .           | .           |
| CV01KP066  | 25 µg<br>(≥71 years) | -1                | -13              | 36.8             | 124                            | 65                              | 86                     | 73.8        | 180.1       |
| CV01KP066  | 25 µg<br>(≥71 years) | 1                 | 1                | 36.9             | 135                            | 81                              | 82                     | .           | .           |
| CV01KP066  | 25 µg<br>(≥71 years) | 8                 | 9                | 36.5             | 124                            | 66                              | 75                     | .           | .           |
| CV01KP066  | 25 µg<br>(≥71 years) | 15                | 16               | 36.7             | 120                            | 74                              | 71                     | .           | .           |
| CV01KP066  | 25 µg<br>(≥71 years) | 29                | 29               | 36.4             | 139                            | 63                              | 75                     | .           | .           |
| CV01KP066  | 25 µg<br>(≥71 years) | 36                | 37               | 36.8             | 124                            | 69                              | 80                     | .           | .           |
| CV01KP066  | 25 µg<br>(≥71 years) | 43                | 44               | 36.8             | 129                            | 72                              | 77                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group     | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-----------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP066  | 25 µg<br>(≥71 years)  | 57                | 57               | 36.7             | 120                            | 63                              | 76                     | .           | .           |
| CV01KP066  | 25 µg<br>(≥71 years)  | 119               | 113              | 36.6             | 127                            | 70                              | 71                     | .           | .           |
| CV01KP067  | 100 µg<br>(≥71 years) | -1                | -14              | 36.9             | 112                            | 56                              | 78                     | 67.4        | 152.5       |
| CV01KP067  | 100 µg<br>(≥71 years) | 1                 | 1                | 36.4             | 122                            | 58                              | 66                     | .           | .           |
| CV01KP067  | 100 µg<br>(≥71 years) | 8                 | 9                | 36.5             | 103                            | 54                              | 65                     | .           | .           |
| CV01KP067  | 100 µg<br>(≥71 years) | 15                | 16               | 36.9             | 109                            | 67                              | 71                     | .           | .           |
| CV01KP067  | 100 µg<br>(≥71 years) | 29                | 29               | 36.7             | 107                            | 51                              | 68                     | .           | .           |
| CV01KP067  | 100 µg<br>(≥71 years) | 36                | 36               | 36.8             | 125                            | 57                              | 62                     | .           | .           |
| CV01KP067  | 100 µg<br>(≥71 years) | 43                | 43               | 36.9             | 113                            | 59                              | 71                     | .           | .           |
| CV01KP067  | 100 µg<br>(≥71 years) | 57                | 57               | 36.9             | 96                             | 52                              | 64                     | .           | .           |
| CV01KP067  | 100 µg<br>(≥71 years) | 119               | 113              | 36.7             | 101                            | 62                              | 71                     | .           | .           |
| CV01KP068  | 25 µg<br>(≥71 years)  | -1                | -14              | 37.1             | 117                            | 68                              | 71                     | 53.3        | 163.6       |
| CV01KP068  | 25 µg<br>(≥71 years)  | 1                 | 1                | 36.6             | 120                            | 69                              | 68                     | .           | .           |
| CV01KP068  | 25 µg<br>(≥71 years)  | 8                 | 9                | 36.6             | 128                            | 73                              | 69                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group    | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|----------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP068  | 25 µg<br>(≥71 years) | 15                | 16               | 36.4             | 122                            | 68                              | 65                     | .           | .           |
| CV01KP068  | 25 µg<br>(≥71 years) | 29                | 29               | 36.7             | 124                            | 72                              | 68                     | .           | .           |
| CV01KP068  | 25 µg<br>(≥71 years) | 36                | 37               | 36.8             | 118                            | 67                              | 71                     | .           | .           |
| CV01KP068  | 25 µg<br>(≥71 years) | 43                | 43               | 36.6             | 139                            | 82                              | 67                     | .           | .           |
| CV01KP068  | 25 µg<br>(≥71 years) | 57                | 57               | 36.6             | 119                            | 67                              | 65                     | .           | .           |
| CV01KP068  | 25 µg<br>(≥71 years) | 119               | 113              | 37.1             | 125                            | 79                              | 64                     | .           | .           |
| CV01KP069  | 25 µg<br>(≥71 years) | -1                | -14              | 37.2             | 125                            | 68                              | 74                     | 78.3        | 164.6       |
| CV01KP069  | 25 µg<br>(≥71 years) | 1                 | 1                | 37               | 139                            | 63                              | 79                     | .           | .           |
| CV01KP069  | 25 µg<br>(≥71 years) | 8                 | 9                | 36.9             | 117                            | 62                              | 63                     | .           | .           |
| CV01KP069  | 25 µg<br>(≥71 years) | 15                | 16               | 36.8             | 114                            | 59                              | 77                     | .           | .           |
| CV01KP069  | 25 µg<br>(≥71 years) | 29                | 29               | 36.8             | 127                            | 59                              | 80                     | .           | .           |
| CV01KP069  | 25 µg<br>(≥71 years) | 36                | 37               | 37.2             | 124                            | 62                              | 73                     | .           | .           |
| CV01KP069  | 25 µg<br>(≥71 years) | 43                | 44               | 37               | 134                            | 70                              | 74                     | .           | .           |
| CV01KP069  | 25 µg<br>(≥71 years) | 57                | 57               | 36.9             | 130                            | 67                              | 84                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group     | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-----------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP069  | 25 µg<br>(≥71 years)  | 119               | 112              | 35.9             | 134                            | 63                              | 77                     | .           | .           |
| CV01KP071  | 100 µg<br>(≥71 years) | -1                | -20              | 36.9             | 143 (Mild)                     | 78                              | 73                     | 60.7        | 156.9       |
| CV01KP071  | 100 µg<br>(≥71 years) | 1                 | 1                | 37.3             | 145 (Mild)                     | 75                              | 72                     | .           | .           |
| CV01KP071  | 100 µg<br>(≥71 years) | 8                 | 8                | 37               | 148 (Mild)                     | 75                              | 73                     | .           | .           |
| CV01KP071  | 100 µg<br>(≥71 years) | 15                | 16               | 36.7             | 130                            | 80                              | 72                     | .           | .           |
| CV01KP071  | 100 µg<br>(≥71 years) | 29                | 28               | 37.1             | 144 (Mild)                     | 77                              | 68                     | .           | .           |
| CV01KP071  | 100 µg<br>(≥71 years) | 36                | 35               | 37.3             | 140                            | 74                              | 67                     | .           | .           |
| CV01KP071  | 100 µg<br>(≥71 years) | 43                | 42               | 37.2             | 130                            | 80                              | 74                     | .           | .           |
| CV01KP071  | 100 µg<br>(≥71 years) | 57                | 56               | 36.8             | 149 (Mild)                     | 84                              | 67                     | .           | .           |
| CV01KP071  | 100 µg<br>(≥71 years) | 119               | 112              | 35.8             | 146 (Mild)                     | 78                              | 68                     | .           | .           |
| CV01KP072  | 25 µg<br>(≥71 years)  | -1                | -12              | 36.7             | 146 (Mild)                     | 70                              | 53 (Mild)              | 80.8        | 178.2       |
| CV01KP072  | 25 µg<br>(≥71 years)  | 1                 | 1                | 36.8             | 119                            | 64                              | 62                     | .           | .           |
| CV01KP072  | 25 µg<br>(≥71 years)  | 8                 | 9                | 36.6             | 136                            | 66                              | 56                     | .           | .           |
| CV01KP072  | 25 µg<br>(≥71 years)  | 15                | 15               | 36.9             | 129                            | 71                              | 58                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group     | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-----------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP072  | 25 µg<br>(≥71 years)  | 29                | 29               | 36.7             | 132                            | 68                              | 55                     | .           | .           |
| CV01KP072  | 25 µg<br>(≥71 years)  | 36                | 37               | 36.9             | 131                            | 66                              | 56                     | .           | .           |
| CV01KP072  | 25 µg<br>(≥71 years)  | 43                | 44               | 37.1             | 111                            | 60                              | 62                     | .           | .           |
| CV01KP072  | 25 µg<br>(≥71 years)  | 57                | 57               | 36.8             | 127                            | 62                              | 52 (Mild)              | .           | .           |
| CV01KP072  | 25 µg<br>(≥71 years)  | 119               | 113              | 36.8             | 124                            | 74                              | 55                     | .           | .           |
| CV01KP073  | 100 µg<br>(≥71 years) | -1                | -12              | 36.8             | 122                            | 67                              | 68                     | 68.4        | 162.8       |
| CV01KP073  | 100 µg<br>(≥71 years) | 1                 | 1                | 36.5             | 117                            | 58                              | 72                     | .           | .           |
| CV01KP073  | 100 µg<br>(≥71 years) | 8                 | 9                | 36.5             | 128                            | 69                              | 65                     | .           | .           |
| CV01KP073  | 100 µg<br>(≥71 years) | 15                | 16               | 36.9             | 129                            | 62                              | 61                     | .           | .           |
| CV01KP073  | 100 µg<br>(≥71 years) | 29                | 29               | 36.7             | 131                            | 65                              | 63                     | .           | .           |
| CV01KP073  | 100 µg<br>(≥71 years) | 36                | 37               | 36.9             | 131                            | 65                              | 62                     | .           | .           |
| CV01KP073  | 100 µg<br>(≥71 years) | 43                | 43               | 36.8             | 115                            | 58                              | 65                     | .           | .           |
| CV01KP073  | 100 µg<br>(≥71 years) | 57                | 58               | 36.9             | 115                            | 56                              | 67                     | .           | .           |
| CV01KP073  | 100 µg<br>(≥71 years) | 119               | 113              | 36.9             | 133                            | 70                              | 63                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group     | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-----------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP075  | 100 µg<br>(≥71 years) | -1                | -18              | 36.7             | 114                            | 56                              | 74                     | 78.7        | 162.8       |
| CV01KP075  | 100 µg<br>(≥71 years) | 1                 | 1                | 37.1             | 118                            | 56                              | 74                     | .           | .           |
| CV01KP075  | 100 µg<br>(≥71 years) | 8                 | 8                | 36.9             | 137                            | 60                              | 83                     | .           | .           |
| CV01KP075  | 100 µg<br>(≥71 years) | 15                | 16               | 36.9             | 121                            | 59                              | 76                     | .           | .           |
| CV01KP075  | 100 µg<br>(≥71 years) | 29                | 29               | 37               | 111                            | 55                              | 72                     | .           | .           |
| CV01KP075  | 100 µg<br>(≥71 years) | 36                | 36               | 36.9             | 115                            | 58                              | 69                     | .           | .           |
| CV01KP075  | 100 µg<br>(≥71 years) | 43                | 43               | 37.2             | 117                            | 58                              | 82                     | .           | .           |
| CV01KP075  | 100 µg<br>(≥71 years) | 57                | 58               | 37.3             | 112                            | 54                              | 73                     | .           | .           |
| CV01KP075  | 100 µg<br>(≥71 years) | 119               | 113              | 36.7             | 119                            | 56                              | 71                     | .           | .           |
| CV01KP076  | 100 µg<br>(≥71 years) | -1                | -19              | 36.6             | 133                            | 74                              | 63                     | 91.2        | 181.7       |
| CV01KP076  | 100 µg<br>(≥71 years) | 1                 | 1                | 36.7             | 136                            | 67                              | 59                     | .           | .           |
| CV01KP076  | 100 µg<br>(≥71 years) | 8                 | 8                | 37.2             | 134                            | 78                              | 73                     | .           | .           |
| CV01KP076  | 100 µg<br>(≥71 years) | 15                | 16               | 37.1             | 118                            | 65                              | 61                     | .           | .           |
| CV01KP076  | 100 µg<br>(≥71 years) | 29                | 28               | 36.7             | 120                            | 62                              | 66                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group     | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-----------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP076  | 100 µg<br>(≥71 years) | 36                | 35               | 36.7             | 122                            | 65                              | 66                     | .           | .           |
| CV01KP076  | 100 µg<br>(≥71 years) | 43                | 42               | 36.8             | 130                            | 75                              | 71                     | .           | .           |
| CV01KP076  | 100 µg<br>(≥71 years) | 57                | 56               | 36.9             | 124                            | 67                              | 83                     | .           | .           |
| CV01KP076  | 100 µg<br>(≥71 years) | 119               | 112              | 35.9             | 120                            | 76                              | 61                     | .           | .           |
| CV01KP077  | 100 µg<br>(≥71 years) | -1                | -19              | 36.9             | 118                            | 53                              | 63                     | 57.9        | 169.6       |
| CV01KP077  | 100 µg<br>(≥71 years) | 1                 | 1                | 36.6             | 116                            | 54                              | 64                     | .           | .           |
| CV01KP077  | 100 µg<br>(≥71 years) | 8                 | 8                | 36.7             | 139                            | 60                              | 63                     | .           | .           |
| CV01KP077  | 100 µg<br>(≥71 years) | 15                | 16               | 36.6             | 127                            | 60                              | 62                     | .           | .           |
| CV01KP077  | 100 µg<br>(≥71 years) | 29                | 28               | 36.7             | 115                            | 55                              | 56                     | .           | .           |
| CV01KP077  | 100 µg<br>(≥71 years) | 36                | 35               | 36.7             | 107                            | 55                              | 63                     | .           | .           |
| CV01KP077  | 100 µg<br>(≥71 years) | 43                | 42               | 36.7             | 118                            | 59                              | 57                     | .           | .           |
| CV01KP077  | 100 µg<br>(≥71 years) | 57                | 56               | 36.7             | 116                            | 51                              | 65                     | .           | .           |
| CV01KP077  | 100 µg<br>(≥71 years) | 119               | 112              | 36.6             | 120                            | 59                              | 55                     | .           | .           |
| CV01KP078  | 100 µg<br>(≥71 years) | -1                | -18              | 37.1             | 118                            | 58                              | 57                     | 62.4        | 171         |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group     | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|-----------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP078  | 100 µg<br>(≥71 years) | 1                 | 1                | 36.7             | 113                            | 75                              | 65                     | .           | .           |
| CV01KP078  | 100 µg<br>(≥71 years) | 8                 | 8                | 36.7             | 127                            | 60                              | 56                     | .           | .           |
| CV01KP078  | 100 µg<br>(≥71 years) | 15                | 16               | 36.5             | 125                            | 66                              | 61                     | .           | .           |
| CV01KP078  | 100 µg<br>(≥71 years) | 29                | 29               | 36.7             | 106                            | 53                              | 60                     | .           | .           |
| CV01KP078  | 100 µg<br>(≥71 years) | 36                | 36               | 36.7             | 116                            | 56                              | 56                     | .           | .           |
| CV01KP078  | 100 µg<br>(≥71 years) | 43                | 43               | 36.8             | 120                            | 56                              | 57                     | .           | .           |
| CV01KP078  | 100 µg<br>(≥71 years) | 57                | 58               | 36.6             | 125                            | 58                              | 54 (Mild)              | .           | .           |
| CV01KP078  | 100 µg<br>(≥71 years) | 119               | 113              | 37.1             | 105                            | 63                              | 72                     | .           | .           |
| CV01KP081  | 100 µg<br>(≥71 years) | -1                | -19              | 36.8             | 134                            | 65                              | 69                     | 71.2        | 173.9       |
| CV01KP081  | 100 µg<br>(≥71 years) | 1                 | 1                | 36.6             | 119                            | 58                              | 60                     | .           | .           |
| CV01KP081  | 100 µg<br>(≥71 years) | 8                 | 8                | 36.8             | 132                            | 70                              | 57                     | .           | .           |
| CV01KP081  | 100 µg<br>(≥71 years) | 15                | 16               | 36.7             | 118                            | 57                              | 61                     | .           | .           |
| CV01KP081  | 100 µg<br>(≥71 years) | 29                | 28               | 36.9             | 113                            | 56                              | 61                     | .           | .           |
| CV01KP081  | 100 µg<br>(≥71 years) | 36                | 35               | 36.4             | 108                            | 56                              | 58                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP081  | 100 µg<br>(≥71 years)  | 43                | 42               | 36.7             | 131                            | 66                              | 60                     | .           | .           |
| CV01KP081  | 100 µg<br>(≥71 years)  | 57                | 57               | 36.6             | 138                            | 67                              | 58                     | .           | .           |
| CV01KP081  | 100 µg<br>(≥71 years)  | 119               | 112              | 36.5             | 121                            | 69                              | 56                     | .           | .           |
| CV01KP085  | 100 µg<br>(≥71 years)  | -1                | -17              | 37.2             | 144 (Mild)                     | 83                              | 78                     | 80          | 165.4       |
| CV01KP085  | 100 µg<br>(≥71 years)  | 1                 | 1                | 37.1             | 132                            | 71                              | 75                     | .           | .           |
| CV01KP085  | 100 µg<br>(≥71 years)  | 8                 | 8                | 36.9             | 142 (Mild)                     | 74                              | 78                     | .           | .           |
| CV01KP085  | 100 µg<br>(≥71 years)  | 15                | 16               | 36.8             | 126                            | 78                              | 82                     | .           | .           |
| CV01KP085  | 100 µg<br>(≥71 years)  | 29                | 29               | 37.2             | 132                            | 74                              | 64                     | .           | .           |
| CV01KP085  | 100 µg<br>(≥71 years)  | 36                | 36               | 36.7             | 126                            | 68                              | 62                     | .           | .           |
| CV01KP085  | 100 µg<br>(≥71 years)  | 43                | 43               | 37               | 140                            | 76                              | 60                     | .           | .           |
| CV01KP085  | 100 µg<br>(≥71 years)  | 57                | 57               | 36.9             | 132                            | 80                              | 60                     | .           | .           |
| CV01KP085  | 100 µg<br>(≥71 years)  | 119               | 113              | 36.2             | 134                            | 78                              | 70                     | .           | .           |
| CV01KP092  | 50 µg<br>(18-55 years) | -1                | -12              | 36.9             | 112                            | 58                              | 51 (Mild)              | 80.4        | 185         |
| CV01KP092  | 50 µg<br>(18-55 years) | 1                 | 1                | 37               | 110                            | 63                              | 58                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP092  | 50 µg<br>(18-55 years) | 8                 | 8                | 36.7             | 119                            | 79                              | 61                     | .           | .           |
| CV01KP092  | 50 µg<br>(18-55 years) | 15                | 15               | 36.7             | 110                            | 70                              | 50 (Mild)              | .           | .           |
| CV01KP092  | 50 µg<br>(18-55 years) | 29                | 27               | 36.9             | 111                            | 58                              | 55                     | .           | .           |
| CV01KP092  | 50 µg<br>(18-55 years) | 36                | 34               | 36.9             | 112                            | 72                              | 58                     | .           | .           |
| CV01KP092  | 50 µg<br>(18-55 years) | 43                | 41               | 36.8             | 123                            | 78                              | 52 (Mild)              | .           | .           |
| CV01KP092  | 50 µg<br>(18-55 years) | 57                | 56               | 36.9             | 118                            | 79                              | 55                     | .           | .           |
| CV01KP094  | 50 µg<br>(18-55 years) | -1                | -8               | 36.5             | 107                            | 58                              | 63                     | 59.6        | 166.1       |
| CV01KP094  | 50 µg<br>(18-55 years) | 1                 | 1                | 36.4             | 98                             | 53                              | 59                     | .           | .           |
| CV01KP094  | 50 µg<br>(18-55 years) | 8                 | 8                | 36.6             | 101                            | 54                              | 56                     | .           | .           |
| CV01KP094  | 50 µg<br>(18-55 years) | 15                | 15               | 36.5             | 97                             | 56                              | 67                     | .           | .           |
| CV01KP094  | 50 µg<br>(18-55 years) | 29                | 27               | 36.7             | 102                            | 60                              | 59                     | .           | .           |
| CV01KP094  | 50 µg<br>(18-55 years) | 36                | 34               | 36.4             | 111                            | 67                              | 56                     | .           | .           |
| CV01KP094  | 50 µg<br>(18-55 years) | 43                | 41               | 36.3             | 93                             | 57                              | 58                     | .           | .           |
| CV01KP094  | 50 µg<br>(18-55 years) | 57                | 55               | 36.5             | 100                            | 60                              | 56                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP094  | 50 µg<br>(18-55 years) | 119               | 112              | 36.8             | 108                            | 68                              | 58                     | .           | .           |
| CV01KP095  | 50 µg<br>(18-55 years) | -1                | -8               | 36.3             | 103                            | 52                              | 57                     | 68.5        | 178.6       |
| CV01KP095  | 50 µg<br>(18-55 years) | 1                 | 1                | 36.7             | 98                             | 54                              | 91                     | .           | .           |
| CV01KP095  | 50 µg<br>(18-55 years) | 8                 | 8                | 36.9             | 107                            | 54                              | 75                     | .           | .           |
| CV01KP095  | 50 µg<br>(18-55 years) | 15                | 15               | 36.6             | 109                            | 55                              | 92                     | .           | .           |
| CV01KP095  | 50 µg<br>(18-55 years) | 29                | 27               | 37               | 106                            | 54                              | 90                     | .           | .           |
| CV01KP095  | 50 µg<br>(18-55 years) | 36                | 34               | 36.9             | 103                            | 57                              | 77                     | .           | .           |
| CV01KP095  | 50 µg<br>(18-55 years) | 43                | 41               | 36.4             | 114                            | 64                              | 76                     | .           | .           |
| CV01KP095  | 50 µg<br>(18-55 years) | 57                | 55               | 36.4             | 107                            | 56                              | 76                     | .           | .           |
| CV01KP095  | 50 µg<br>(18-55 years) | 119               | 112              | 36.6             | 96                             | 55                              | 94                     | .           | .           |
| CV01KP096  | 50 µg<br>(18-55 years) | -1                | -8               | 36.7             | 133                            | 70                              | 61                     | 73.7        | 180.4       |
| CV01KP096  | 50 µg<br>(18-55 years) | 1                 | 1                | 36.9             | 122                            | 60                              | 61                     | .           | .           |
| CV01KP096  | 50 µg<br>(18-55 years) | 8                 | 8                | 36.9             | 121                            | 58                              | 69                     | .           | .           |
| CV01KP096  | 50 µg<br>(18-55 years) | 15                | 15               | 36.9             | 127                            | 74                              | 62                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP096  | 50 µg<br>(18-55 years) | 29                | 27               | 36.9             | 120                            | 61                              | 62                     | .           | .           |
| CV01KP096  | 50 µg<br>(18-55 years) | 36                | 36               | 37.1             | 115                            | 75                              | 51 (Mild)              | .           | .           |
| CV01KP096  | 50 µg<br>(18-55 years) | 43                | 41               | 37               | 115                            | 66                              | 63                     | .           | .           |
| CV01KP096  | 50 µg<br>(18-55 years) | 57                | 55               | 36.7             | 124                            | 82                              | 70                     | .           | .           |
| CV01KP096  | 50 µg<br>(18-55 years) | 119               | 112              | 36.6             | 118                            | 76                              | 63                     | .           | .           |
| CV01KP097  | 50 µg<br>(18-55 years) | -1                | -8               | 36.9             | 125                            | 78                              | 62                     | 78.2        | 184.6       |
| CV01KP097  | 50 µg<br>(18-55 years) | 1                 | 1                | 36.6             | 119                            | 67                              | 52 (Mild)              | .           | .           |
| CV01KP097  | 50 µg<br>(18-55 years) | 8                 | 8                | 36.4             | 118                            | 75                              | 55                     | .           | .           |
| CV01KP097  | 50 µg<br>(18-55 years) | 15                | 15               | 36.5             | 126                            | 67                              | 60                     | .           | .           |
| CV01KP097  | 50 µg<br>(18-55 years) | 29                | 27               | 36.8             | 133                            | 75                              | 56                     | .           | .           |
| CV01KP097  | 50 µg<br>(18-55 years) | 36                | 34               | 36.4             | 124                            | 78                              | 57                     | .           | .           |
| CV01KP097  | 50 µg<br>(18-55 years) | 43                | 41               | 36.7             | 124                            | 66                              | 58                     | .           | .           |
| CV01KP097  | 50 µg<br>(18-55 years) | 57                | 55               | 36.5             | 129                            | 81                              | 56                     | .           | .           |
| CV01KP098  | 50 µg<br>(18-55 years) | -1                | -7               | 37.1             | 115                            | 58                              | 64                     | 84.7        | 178.2       |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP098  | 50 µg<br>(18-55 years) | 1                 | 1                | 36.9             | 108                            | 55                              | 60                     | .           | .           |
| CV01KP098  | 50 µg<br>(18-55 years) | 8                 | 8                | 36.7             | 115                            | 63                              | 59                     | .           | .           |
| CV01KP098  | 50 µg<br>(18-55 years) | 15                | 15               | 36.9             | 117                            | 57                              | 55                     | .           | .           |
| CV01KP098  | 50 µg<br>(18-55 years) | 29                | 27               | 36.9             | 121                            | 58                              | 58                     | .           | .           |
| CV01KP098  | 50 µg<br>(18-55 years) | 36                | 34               | 37               | 107                            | 58                              | 52 (Mild)              | .           | .           |
| CV01KP098  | 50 µg<br>(18-55 years) | 43                | 41               | 36.8             | 125                            | 60                              | 61                     | .           | .           |
| CV01KP098  | 50 µg<br>(18-55 years) | 57                | 55               | 37.1             | 118                            | 59                              | 56                     | .           | .           |
| CV01KP101  | 50 µg<br>(18-55 years) | -1                | -7               | 37.1             | 101                            | 62                              | 66                     | 76          | 185.2       |
| CV01KP101  | 50 µg<br>(18-55 years) | 1                 | 1                | 36.7             | 109                            | 66                              | 66                     | .           | .           |
| CV01KP101  | 50 µg<br>(18-55 years) | 8                 | 8                | 36.6             | 98                             | 56                              | 62                     | .           | .           |
| CV01KP101  | 50 µg<br>(18-55 years) | 15                | 15               | 36.5             | 105                            | 65                              | 58                     | .           | .           |
| CV01KP101  | 50 µg<br>(18-55 years) | 29                | 27               | 36.6             | 111                            | 60                              | 58                     | .           | .           |
| CV01KP101  | 50 µg<br>(18-55 years) | 36                | 34               | 36.9             | 112                            | 59                              | 64                     | .           | .           |
| CV01KP101  | 50 µg<br>(18-55 years) | 43                | 41               | 36.8             | 110                            | 63                              | 68                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01KP101  | 50 µg<br>(18-55 years) | 57                | 55               | 37.1             | 119                            | 67                              | 87                     | .           | .           |
| CV01VR002  | 50 µg<br>(≥71 years)   | -1                | -38              | 36.1             | 141 (Mild)                     | 63                              | 48 (Moderate)          | 81.5        | 188         |
| CV01VR002  | 50 µg<br>(≥71 years)   | 1                 | 1                | 36.1             | 143 (Mild)                     | 67                              | 60                     | .           | .           |
| CV01VR002  | 50 µg<br>(≥71 years)   | 8                 | 7                | 36.1             | 124                            | 64                              | 53 (Mild)              | .           | .           |
| CV01VR002  | 50 µg<br>(≥71 years)   | 15                | 13               | 36.8             | 126                            | 60                              | 60                     | .           | .           |
| CV01VR002  | 50 µg<br>(≥71 years)   | 29                | 27               | 36.1             | 130                            | 70                              | 60                     | .           | .           |
| CV01VR002  | 50 µg<br>(≥71 years)   | 36                | 35               | 36.8             | 125                            | 67                              | 62                     | .           | .           |
| CV01VR002  | 50 µg<br>(≥71 years)   | 43                | 41               | 36.1             | 137                            | 66                              | 54 (Mild)              | .           | .           |
| CV01VR002  | 50 µg<br>(≥71 years)   | 57                | 55               | 36.2             | 126                            | 63                              | 60                     | .           | .           |
| CV01VR002  | 50 µg<br>(≥71 years)   | 119               | 117              | 36.2             | 137                            | 69                              | 54 (Mild)              | .           | .           |
| CV01VR003  | 50 µg<br>(56-70 years) | -1                | -35              | 36.1             | 109                            | 73                              | 63                     | 66.1        | 169         |
| CV01VR003  | 50 µg<br>(56-70 years) | 1                 | 1                | 36.1             | 112                            | 67                              | 60                     | .           | .           |
| CV01VR003  | 50 µg<br>(56-70 years) | 8                 | 7                | 36.1             | 112                            | 69                              | 63                     | .           | .           |
| CV01VR003  | 50 µg<br>(56-70 years) | 15                | 15               | 36.1             | 104                            | 67                              | 67                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01VR003  | 50 µg<br>(56-70 years) | 29                | 31               | 36.1             | 103                            | 61                              | 67                     | .           | .           |
| CV01VR003  | 50 µg<br>(56-70 years) | 36                | 37               | 36.1             | 115                            | 66                              | 61                     | .           | .           |
| CV01VR003  | 50 µg<br>(56-70 years) | 43                | 45               | 36.1             | 103                            | 64                              | 57                     | .           | .           |
| CV01VR003  | 50 µg<br>(56-70 years) | 57                | 59               | 36.3             | 112                            | 74                              | 58                     | .           | .           |
| CV01VR003  | 50 µg<br>(56-70 years) | 119               | 121              | 36.1             | 109                            | 68                              | 58                     | .           | .           |
| CV01VR004  | 50 µg<br>(≥71 years)   | -1                | -37              | 36.1             | 128                            | 69                              | 60                     | 86.2        | 178         |
| CV01VR004  | 50 µg<br>(≥71 years)   | 1                 | 1                | 36.1             | 129                            | 62                              | 51 (Mild)              | .           | .           |
| CV01VR004  | 50 µg<br>(≥71 years)   | 8                 | 7                | 36.1             | 112                            | 67                              | 66                     | .           | .           |
| CV01VR004  | 50 µg<br>(≥71 years)   | 15                | 15               | 36.1             | 131                            | 75                              | 55                     | .           | .           |
| CV01VR004  | 50 µg<br>(≥71 years)   | 29                | 27               | 36.1             | 127                            | 73                              | 56                     | .           | .           |
| CV01VR004  | 50 µg<br>(≥71 years)   | 36                | 33               | 36.1             | 122                            | 70                              | 56                     | .           | .           |
| CV01VR004  | 50 µg<br>(≥71 years)   | 43                | 41               | 36.1             | 122                            | 70                              | 55                     | .           | .           |
| CV01VR004  | 50 µg<br>(≥71 years)   | 57                | 57               | 36.1             | 125                            | 75                              | 67                     | .           | .           |
| CV01VR004  | 50 µg<br>(≥71 years)   | 119               | 117              | 36.1             | 116                            | 65                              | 60                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01VR005  | 50 µg<br>(56-70 years) | -1                | -36              | 36.1             | 121                            | 67                              | 62                     | 73.6        | 177         |
| CV01VR005  | 50 µg<br>(56-70 years) | 1                 | 1                | 36.1             | 134                            | 70                              | 61                     | .           | .           |
| CV01VR005  | 50 µg<br>(56-70 years) | 8                 | 7                | 36.1             | 127                            | 72                              | 59                     | .           | .           |
| CV01VR005  | 50 µg<br>(56-70 years) | 15                | 15               | 36.1             | 111                            | 64                              | 58                     | .           | .           |
| CV01VR005  | 50 µg<br>(56-70 years) | 29                | 27               | 36.1             | 127                            | 71                              | 52 (Mild)              | .           | .           |
| CV01VR005  | 50 µg<br>(56-70 years) | 36                | 33               | 36.1             | 124                            | 69                              | 63                     | .           | .           |
| CV01VR005  | 50 µg<br>(56-70 years) | 43                | 41               | 36.1             | 126                            | 75                              | 55                     | .           | .           |
| CV01VR005  | 50 µg<br>(56-70 years) | 57                | 55               | 36.1             | 113                            | 73                              | 55                     | .           | .           |
| CV01VR005  | 50 µg<br>(56-70 years) | 119               | 117              | 35.6             | 133                            | 76                              | 56                     | .           | .           |
| CV01VR006  | 50 µg<br>(56-70 years) | -1                | -34              | 36.1             | 133                            | 74                              | 61                     | 82          | 182         |
| CV01VR006  | 50 µg<br>(56-70 years) | 1                 | 1                | 35.6             | 142 (Mild)                     | 77                              | 65                     | .           | .           |
| CV01VR006  | 50 µg<br>(56-70 years) | 8                 | 7                | 36.1             | 134                            | 73                              | 74                     | .           | .           |
| CV01VR006  | 50 µg<br>(56-70 years) | 15                | 15               | 36.1             | 127                            | 80                              | 67                     | .           | .           |
| CV01VR006  | 50 µg<br>(56-70 years) | 29                | 31               | 36.1             | 126                            | 72                              | 64                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01VR006  | 50 µg<br>(56-70 years) | 36                | 37               | 36.1             | 121                            | 66                              | 62                     | .           | .           |
| CV01VR006  | 50 µg<br>(56-70 years) | 43                | 45               | 36.1             | 130                            | 72                              | 64                     | .           | .           |
| CV01VR006  | 50 µg<br>(56-70 years) | 57                | 59               | 36.1             | 138                            | 75                              | 65                     | .           | .           |
| CV01VR006  | 50 µg<br>(56-70 years) | 119               | 121              | 36.1             | 133                            | 78                              | 76                     | .           | .           |
| CV01VR008  | 50 µg<br>(56-70 years) | -1                | -34              | 36.2             | 129                            | 69                              | 88                     | 70.2        | 179         |
| CV01VR008  | 50 µg<br>(56-70 years) | .                 | -26              | 36.2             | 132                            | 76                              | 76                     | .           | .           |
| CV01VR008  | 50 µg<br>(56-70 years) | 1                 | 1                | 36.3             | 118                            | 63                              | 71                     | .           | .           |
| CV01VR008  | 50 µg<br>(56-70 years) | 8                 | 7                | 36.1             | 119                            | 70                              | 79                     | .           | .           |
| CV01VR008  | 50 µg<br>(56-70 years) | 15                | 15               | 35.7             | 116                            | 71                              | 75                     | .           | .           |
| CV01VR008  | 50 µg<br>(56-70 years) | 29                | 31               | 36.1             | 116                            | 71                              | 68                     | .           | .           |
| CV01VR008  | 50 µg<br>(56-70 years) | 36                | 37               | 36.1             | 121                            | 81                              | 65                     | .           | .           |
| CV01VR008  | 50 µg<br>(56-70 years) | 43                | 45               | 36.1             | 118                            | 68                              | 65                     | .           | .           |
| CV01VR008  | 50 µg<br>(56-70 years) | 57                | 59               | 36.1             | 126                            | 78                              | 66                     | .           | .           |
| CV01VR008  | 50 µg<br>(56-70 years) | 119               | 121              | 36.1             | 111                            | 73                              | 79                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01VR009  | 50 µg<br>(56-70 years) | -1                | -35              | 36.1             | 115                            | 62                              | 60                     | 54          | 160         |
| CV01VR009  | 50 µg<br>(56-70 years) | 1                 | 1                | 36.2             | 115                            | 53                              | 54 (Mild)              | .           | .           |
| CV01VR009  | 50 µg<br>(56-70 years) | 8                 | 7                | 36.6             | 113                            | 64                              | 54 (Mild)              | .           | .           |
| CV01VR009  | 50 µg<br>(56-70 years) | 15                | 13               | 36               | 111                            | 59                              | 64                     | .           | .           |
| CV01VR009  | 50 µg<br>(56-70 years) | 29                | 27               | 36.1             | 116                            | 59                              | 68                     | .           | .           |
| CV01VR009  | 50 µg<br>(56-70 years) | 36                | 35               | 36.1             | 117                            | 60                              | 60                     | .           | .           |
| CV01VR009  | 50 µg<br>(56-70 years) | 43                | 41               | 36.1             | 107                            | 58                              | 62                     | .           | .           |
| CV01VR009  | 50 µg<br>(56-70 years) | 57                | 55               | 36.8             | 126                            | 63                              | 56                     | .           | .           |
| CV01VR009  | 50 µg<br>(56-70 years) | 119               | 118              | 36.1             | 135                            | 68                              | 55                     | .           | .           |
| CV01VR011  | 50 µg<br>(56-70 years) | -1                | -33              | 35.9             | 130                            | 81                              | 66                     | 81.5        | 186.7       |
| CV01VR011  | 50 µg<br>(56-70 years) | 1                 | 1                | 36.6             | 119                            | 68                              | 58                     | .           | .           |
| CV01VR011  | 50 µg<br>(56-70 years) | 8                 | 7                | 36.1             | 127                            | 66                              | 61                     | .           | .           |
| CV01VR011  | 50 µg<br>(56-70 years) | 15                | 15               | 36.1             | 119                            | 63                              | 61                     | .           | .           |
| CV01VR011  | 50 µg<br>(56-70 years) | 29                | 31               | 36.1             | 134                            | 62                              | 64                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01VR011  | 50 µg<br>(56-70 years) | 36                | 37               | 36.6             | 103                            | 52                              | 59                     | .           | .           |
| CV01VR011  | 50 µg<br>(56-70 years) | 43                | 43               | 36.1             | 135                            | 69                              | 62                     | .           | .           |
| CV01VR011  | 50 µg<br>(56-70 years) | 57                | 59               | 36.4             | 137                            | 61                              | 73                     | .           | .           |
| CV01VR011  | 50 µg<br>(56-70 years) | 119               | 121              | 36.1             | 130                            | 65                              | 58                     | .           | .           |
| CV01VR013  | 50 µg<br>(≥71 years)   | -1                | -35              | 36.1             | 133                            | 69                              | 49 (Moderate)          | 83          | 186         |
| CV01VR013  | 50 µg<br>(≥71 years)   | 1                 | 1                | 36.1             | 137                            | 62                              | 51 (Mild)              | .           | .           |
| CV01VR013  | 50 µg<br>(≥71 years)   | 8                 | 7                | 36.1             | 138                            | 66                              | 51 (Mild)              | .           | .           |
| CV01VR013  | 50 µg<br>(≥71 years)   | 15                | 15               | 36.1             | 139                            | 67                              | 53 (Mild)              | .           | .           |
| CV01VR013  | 50 µg<br>(≥71 years)   | 29                | 27               | 36.1             | 136                            | 63                              | 56                     | .           | .           |
| CV01VR013  | 50 µg<br>(≥71 years)   | 36                | 33               | 36.1             | 134                            | 68                              | 53 (Mild)              | .           | .           |
| CV01VR013  | 50 µg<br>(≥71 years)   | 43                | 41               | 36.1             | 129                            | 61                              | 51 (Mild)              | .           | .           |
| CV01VR013  | 50 µg<br>(≥71 years)   | 57                | 55               | 36.1             | 138                            | 67                              | 51 (Mild)              | .           | .           |
| CV01VR013  | 50 µg<br>(≥71 years)   | 119               | 117              | 35.7             | 136                            | 65                              | 50 (Mild)              | .           | .           |
| CV01VR014  | 50 µg<br>(≥71 years)   | -1                | -34              | 36.4             | 117                            | 66                              | 66                     | 71          | 168         |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01VR014  | 50 µg<br>(≥71 years)   | 1                 | 1                | 36.1             | 111                            | 75                              | 67                     | .           | .           |
| CV01VR014  | 50 µg<br>(≥71 years)   | 8                 | 7                | 36.1             | 116                            | 70                              | 64                     | .           | .           |
| CV01VR014  | 50 µg<br>(≥71 years)   | 15                | 15               | 36.1             | 109                            | 70                              | 66                     | .           | .           |
| CV01VR014  | 50 µg<br>(≥71 years)   | 29                | 27               | 36.1             | 113                            | 68                              | 69                     | .           | .           |
| CV01VR014  | 50 µg<br>(≥71 years)   | 36                | 33               | 36.1             | 107                            | 67                              | 63                     | .           | .           |
| CV01VR014  | 50 µg<br>(≥71 years)   | 43                | 41               | 36.1             | 103                            | 75                              | 62                     | .           | .           |
| CV01VR014  | 50 µg<br>(≥71 years)   | 57                | 55               | 36.1             | 110                            | 75                              | 66                     | .           | .           |
| CV01VR014  | 50 µg<br>(≥71 years)   | 119               | 117              | 36.1             | 121                            | 63                              | 70                     | .           | .           |
| CV01VR016  | 50 µg<br>(56-70 years) | -1                | -33              | 36.2             | 116                            | 76                              | 62                     | 66.1        | 170.2       |
| CV01VR016  | 50 µg<br>(56-70 years) | .                 | -21              | 36.5             | 111                            | 72                              | 67                     | 66.1        | 170.2       |
| CV01VR016  | 50 µg<br>(56-70 years) | 1                 | 1                | 36.1             | 102                            | 74                              | 64                     | .           | .           |
| CV01VR016  | 50 µg<br>(56-70 years) | 8                 | 7                | 36.2             | 106                            | 62                              | 61                     | .           | .           |
| CV01VR016  | 50 µg<br>(56-70 years) | 15                | 13               | 36.1             | 120                            | 80                              | 72                     | .           | .           |
| CV01VR016  | 50 µg<br>(56-70 years) | 29                | 27               | 36.2             | 107                            | 65                              | 60                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01VR016  | 50 µg<br>(56-70 years) | 36                | 35               | 36.5             | 98                             | 62                              | 64                     | .           | .           |
| CV01VR016  | 50 µg<br>(56-70 years) | 43                | 41               | 36.3             | 100                            | 60                              | 68                     | .           | .           |
| CV01VR016  | 50 µg<br>(56-70 years) | 57                | 55               | 36.9             | 104                            | 60                              | 61                     | .           | .           |
| CV01VR016  | 50 µg<br>(56-70 years) | 119               | 118              | 36.1             | 100                            | 58                              | 66                     | .           | .           |
| CV01VR017  | 50 µg<br>(56-70 years) | -1                | -33              | 36.8             | 130                            | 90                              | 90                     | 52          | 157.5       |
| CV01VR017  | 50 µg<br>(56-70 years) | 1                 | 1                | 37.3             | 140                            | 85                              | 86                     | .           | .           |
| CV01VR017  | 50 µg<br>(56-70 years) | 8                 | 7                | 36.9             | 130                            | 80                              | 82                     | .           | .           |
| CV01VR017  | 50 µg<br>(56-70 years) | 15                | 13               | 36.2             | 112                            | 76                              | 82                     | .           | .           |
| CV01VR017  | 50 µg<br>(56-70 years) | 29                | 27               | 37.2             | 129                            | 85                              | 75                     | .           | .           |
| CV01VR017  | 50 µg<br>(56-70 years) | 36                | 35               | 36.2             | 119                            | 73                              | 89                     | .           | .           |
| CV01VR017  | 50 µg<br>(56-70 years) | 43                | 41               | 36.2             | 110                            | 75                              | 92                     | .           | .           |
| CV01VR017  | 50 µg<br>(56-70 years) | 57                | 55               | 36.4             | 117                            | 82                              | 86                     | .           | .           |
| CV01VR017  | 50 µg<br>(56-70 years) | 119               | 118              | 36.1             | 115                            | 76                              | 88                     | .           | .           |
| CV01VR018  | 50 µg<br>(≥71 years)   | -1                | -34              | 36.1             | 122                            | 86                              | 62                     | 66          | 174         |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group    | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|----------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01VR018  | 50 µg<br>(≥71 years) | 1                 | 1                | 36.9             | 108                            | 72                              | 65                     | .           | .           |
| CV01VR018  | 50 µg<br>(≥71 years) | 8                 | 7                | 36.6             | 107                            | 76                              | 69                     | .           | .           |
| CV01VR018  | 50 µg<br>(≥71 years) | 15                | 15               | 36.1             | 112                            | 72                              | 77                     | .           | .           |
| CV01VR018  | 50 µg<br>(≥71 years) | 29                | 27               | 36.3             | 107                            | 70                              | 70                     | .           | .           |
| CV01VR018  | 50 µg<br>(≥71 years) | 36                | 33               | 36.1             | 115                            | 78                              | 79                     | .           | .           |
| CV01VR018  | 50 µg<br>(≥71 years) | 43                | 41               | 36.3             | 117                            | 73                              | 79                     | .           | .           |
| CV01VR018  | 50 µg<br>(≥71 years) | 57                | 55               | 37               | 131                            | 75                              | 78                     | .           | .           |
| CV01VR018  | 50 µg<br>(≥71 years) | 119               | 117              | 36.2             | 112                            | 69                              | 76                     | .           | .           |
| CV01VR021  | 50 µg<br>(≥71 years) | -1                | -31              | 36.4             | 145 (Mild)                     | 82                              | 73                     | 75.1        | 165         |
| CV01VR021  | 50 µg<br>(≥71 years) | 1                 | 1                | 36.1             | 130                            | 75                              | 74                     | .           | .           |
| CV01VR021  | 50 µg<br>(≥71 years) | 8                 | 7                | 36.3             | 132                            | 77                              | 74                     | .           | .           |
| CV01VR021  | 50 µg<br>(≥71 years) | 15                | 13               | 36.1             | 131                            | 80                              | 75                     | .           | .           |
| CV01VR021  | 50 µg<br>(≥71 years) | 29                | 27               | 36.5             | 148 (Mild)                     | 85                              | 85                     | .           | .           |
| CV01VR021  | 50 µg<br>(≥71 years) | 36                | 35               | 36.2             | 144 (Mild)                     | 80                              | 84                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01VR021  | 50 µg<br>(≥71 years)   | 43                | 41               | 36.3             | 140                            | 94 (Mild)                       | 73                     | .           | .           |
| CV01VR021  | 50 µg<br>(≥71 years)   | 57                | 55               | 36.1             | 135                            | 77                              | 76                     | .           | .           |
| CV01VR021  | 50 µg<br>(≥71 years)   | 119               | 117              | 36.2             | 128                            | 64                              | 92                     | .           | .           |
| CV01VR023  | 50 µg<br>(≥71 years)   | -1                | -28              | 36.3             | 126                            | 67                              | 62                     | 56.3        | 165.1       |
| CV01VR023  | 50 µg<br>(≥71 years)   | 1                 | 1                | 36.1             | 107                            | 62                              | 65                     | .           | .           |
| CV01VR023  | 50 µg<br>(≥71 years)   | 8                 | 7                | 36.1             | 122                            | 67                              | 68                     | .           | .           |
| CV01VR023  | 50 µg<br>(≥71 years)   | 15                | 15               | 36.2             | 136                            | 73                              | 60                     | .           | .           |
| CV01VR023  | 50 µg<br>(≥71 years)   | 29                | 31               | 36.1             | 129                            | 76                              | 59                     | .           | .           |
| CV01VR023  | 50 µg<br>(≥71 years)   | 36                | 37               | 36.1             | 124                            | 81                              | 62                     | .           | .           |
| CV01VR023  | 50 µg<br>(≥71 years)   | 43                | 45               | 36.1             | 130                            | 71                              | 61                     | .           | .           |
| CV01VR023  | 50 µg<br>(≥71 years)   | 57                | 59               | 36.1             | 123                            | 67                              | 57                     | .           | .           |
| CV01VR023  | 50 µg<br>(≥71 years)   | 119               | 121              | 36.2             | 130                            | 61                              | 59                     | .           | .           |
| CV01VR024  | 50 µg<br>(56-70 years) | -1                | -27              | 36.9             | 129                            | 81                              | 88                     | 87          | 177         |
| CV01VR024  | 50 µg<br>(56-70 years) | 1                 | 1                | 36.5             | 118                            | 74                              | 89                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01VR024  | 50 µg<br>(56-70 years) | 8                 | 7                | 36.1             | 113                            | 79                              | 83                     | .           | .           |
| CV01VR024  | 50 µg<br>(56-70 years) | 15                | 15               | 36.1             | 112                            | 76                              | 86                     | .           | .           |
| CV01VR024  | 50 µg<br>(56-70 years) | 29                | 31               | 36.2             | 121                            | 79                              | 86                     | .           | .           |
| CV01VR024  | 50 µg<br>(56-70 years) | 36                | 37               | 36.1             | 111                            | 71                              | 85                     | .           | .           |
| CV01VR024  | 50 µg<br>(56-70 years) | 43                | 45               | 36.1             | 129                            | 72                              | 77                     | .           | .           |
| CV01VR024  | 50 µg<br>(56-70 years) | 57                | 59               | 37.2             | 100                            | 68                              | 93                     | .           | .           |
| CV01VR024  | 50 µg<br>(56-70 years) | 119               | 127              | 36.1             | 107                            | 76                              | 77                     | .           | .           |
| CV01VR028  | 50 µg<br>(56-70 years) | -1                | -28              | 36.5             | 133                            | 83                              | 80                     | 78          | 177.8       |
| CV01VR028  | 50 µg<br>(56-70 years) | 1                 | 1                | 36.1             | 107                            | 77                              | 83                     | .           | .           |
| CV01VR028  | 50 µg<br>(56-70 years) | 8                 | 7                | 35.7             | 98                             | 63                              | 68                     | .           | .           |
| CV01VR028  | 50 µg<br>(56-70 years) | 15                | 15               | 36.1             | 97                             | 68                              | 78                     | .           | .           |
| CV01VR028  | 50 µg<br>(56-70 years) | 29                | 27               | 36.1             | 106                            | 67                              | 71                     | .           | .           |
| CV01VR028  | 50 µg<br>(56-70 years) | 36                | 33               | 35.7             | 115                            | 68                              | 86                     | .           | .           |
| CV01VR028  | 50 µg<br>(56-70 years) | 43                | 41               | 36.1             | 112                            | 67                              | 80                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group      | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|------------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01VR028  | 50 µg<br>(56-70 years) | 57                | 55               | 36.1             | 107                            | 71                              | 71                     | .           | .           |
| CV01VR028  | 50 µg<br>(56-70 years) | 119               | 117              | 36.1             | 119                            | 71                              | 65                     | .           | .           |
| CV01VR030  | 50 µg<br>(≥71 years)   | -1                | -27              | 36.1             | 118                            | 68                              | 67                     | 77          | 162.6       |
| CV01VR030  | 50 µg<br>(≥71 years)   | 1                 | 1                | 36.3             | 113                            | 72                              | 72                     | .           | .           |
| CV01VR030  | 50 µg<br>(≥71 years)   | 8                 | 7                | 36.2             | 137                            | 78                              | 84                     | .           | .           |
| CV01VR030  | 50 µg<br>(≥71 years)   | 15                | 13               | 36.5             | 117                            | 71                              | 63                     | .           | .           |
| CV01VR030  | 50 µg<br>(≥71 years)   | 29                | 27               | 36.1             | 113                            | 73                              | 82                     | .           | .           |
| CV01VR030  | 50 µg<br>(≥71 years)   | 36                | 35               | 36.2             | 114                            | 77                              | 56                     | .           | .           |
| CV01VR030  | 50 µg<br>(≥71 years)   | 43                | 41               | 36               | 134                            | 77                              | 79                     | .           | .           |
| CV01VR030  | 50 µg<br>(≥71 years)   | 57                | 55               | 37               | 122                            | 77                              | 86                     | .           | .           |
| CV01VR030  | 50 µg<br>(≥71 years)   | 119               | 118              | 36.1             | 119                            | 78                              | 94                     | .           | .           |
| CV01VR035  | 50 µg<br>(≥71 years)   | -1                | -23              | 36.2             | 130                            | 71                              | 71                     | 65.5        | 161         |
| CV01VR035  | 50 µg<br>(≥71 years)   | 1                 | 1                | 36.2             | 120                            | 66                              | 76                     | .           | .           |
| CV01VR035  | 50 µg<br>(≥71 years)   | 8                 | 7                | 36.1             | 120                            | 60                              | 82                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| Subject ID | Vaccination Group    | Planned Study Day | Actual Study Day | Temperature (°C) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Heart Rate (beats/min) | Weight (kg) | Height (cm) |
|------------|----------------------|-------------------|------------------|------------------|--------------------------------|---------------------------------|------------------------|-------------|-------------|
| CV01VR035  | 50 µg<br>(≥71 years) | 15                | 13               | 36.1             | 117                            | 62                              | 85                     | .           | .           |
| CV01VR035  | 50 µg<br>(≥71 years) | 29                | 27               | 36.1             | 112                            | 62                              | 77                     | .           | .           |
| CV01VR035  | 50 µg<br>(≥71 years) | 36                | 35               | 36.7             | 108                            | 70                              | 77                     | .           | .           |
| CV01VR035  | 50 µg<br>(≥71 years) | 43                | 41               | 36.9             | 123                            | 67                              | 70                     | .           | .           |
| CV01VR035  | 50 µg<br>(≥71 years) | 57                | 55               | 36.8             | 115                            | 64                              | 74                     | .           | .           |
| CV01VR035  | 50 µg<br>(≥71 years) | 119               | 117              | 36.1             | 107                            | 63                              | 85                     | .           | .           |
| CV01VR037  | 50 µg<br>(≥71 years) | -1                | -23              | 36.5             | 148 (Mild)                     | 73                              | 87                     | 67          | 172         |
| CV01VR037  | 50 µg<br>(≥71 years) | 1                 | 1                | 36.1             | 129                            | 67                              | 77                     | .           | .           |
| CV01VR037  | 50 µg<br>(≥71 years) | 8                 | 7                | 36.5             | 108                            | 76                              | 70                     | .           | .           |
| CV01VR037  | 50 µg<br>(≥71 years) | 15                | 13               | 36.3             | 128                            | 68                              | 86                     | .           | .           |
| CV01VR037  | 50 µg<br>(≥71 years) | 29                | 27               | 36.2             | 124                            | 74                              | 81                     | .           | .           |
| CV01VR037  | 50 µg<br>(≥71 years) | 36                | 35               | 36.1             | 120                            | 60                              | 80                     | .           | .           |
| CV01VR037  | 50 µg<br>(≥71 years) | 43                | 41               | 36.4             | 122                            | 64                              | 82                     | .           | .           |
| CV01VR037  | 50 µg<br>(≥71 years) | 57                | 55               | 36.8             | 120                            | 72                              | 83                     | .           | .           |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix F (continued)**  
**Vital Signs Listing**

| <b>Subject ID</b> | <b>Vaccination Group</b> | <b>Planned Study Day</b> | <b>Actual Study Day</b> | <b>Temperature (°C)</b> | <b>Systolic Blood Pressure (mmHg)</b> | <b>Diastolic Blood Pressure (mmHg)</b> | <b>Heart Rate (beats/min)</b> | <b>Weight (kg)</b> | <b>Height (cm)</b> |
|-------------------|--------------------------|--------------------------|-------------------------|-------------------------|---------------------------------------|--|-------------------------------|--------------------|--------------------|
| CV01VR037         | 50 µg<br>(≥71 years)     | 119                      | 117                     | 35.9                    | 110                                   | 49                                     | 84                            | .                  | .                  |

**APPENDIX G1:**  
**Listing of Protocol Deviations**

| Subject ID | Vaccination Group    | Deviation Number | Deviation                 | Deviation Category             | Study Day | Reason for Deviation           | Deviation Resulted in AE? | Deviation Resulted in Subject Termination? | Deviation Affected Product Stability? | Deviation Resolution  | Comments  |
|------------|----------------------|------------------|---------------------------|--------------------------------|-----------|--------------------------------|---------------------------|--|---------------------------------------|---|---|
| CV01EM003  | 250 µg (18-55 years) | 1                | Too few aliquots obtained | Protocol procedure /assessment | 1         | Subject unable to comply       | No                        | No   | No                                    | subject instructed to eat and hydrate well before clinic visit                          |   |
| CV01EM003  | 250 µg (18-55 years) | 2                | Too few aliquots obtained | Protocol procedure /assessment | 36        | Other: Poor quality PBMC layer | No                        | No   | No                                    | Deviation not due to human error  |   |
| CV01EM004  | 100 µg (18-55 years) | 1                | Too few aliquots obtained | Protocol procedure /assessment | 1         | Subject unable to comply       | No                        | No   | No                                    | Not enough blood sample after multiple sticks. Subject will be advised to hydrate more. |   |
| CV01EM005  | 100 µg (18-55 years) | 1                | Too few aliquots obtained | Protocol procedure /assessment | 1         | Other: Poor quality PBMC layer | No                        | No   | No                                    | Deviation not due to human error  |   |
| CV01EM005  | 100 µg (18-55 years) | 2                | Too few aliquots obtained | Protocol procedure /assessment | 28        | Other: Poor quality PBMC layer | No                        | No   | No                                    | Deviation not due to human error  |   |
| CV01EM007  | 100 µg (18-55 years) | 1                | Too few aliquots obtained | Protocol procedure /assessment | 1         | Laboratory error               | No                        | No   | No                                    | Rinse more CPT tubes to collect buffy coat layer  | Suspected that the entire buffy coat wasn't collected |
| CV01EM007  | 100 µg (18-55 years) | 2                | Too few aliquots obtained | Protocol procedure /assessment | 28        | Other: Poor quality PBMC layer | No                        | No   | No                                    | Deviation not due to human error  |   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix G1 (continued)**  
**Listing of Protocol Deviations**

| Subject ID | Vaccination Group    | Deviation Number | Deviation                           | Deviation Category             | Study Day | Reason for Deviation           | Deviation Resulted in AE? | Deviation Resulted in Subject Termination? | Deviation Affected Product Stability? | Deviation Resolution  | Comments  |
|------------|----------------------|------------------|-------------------------------------|--------------------------------|-----------|--------------------------------|---------------------------|--|---------------------------------------|---|---|
| CV01EM007  | 100 µg (18-55 years) | 3                | Too few aliquots obtained           | Protocol procedure /assessment | 34        | Other: Poor quality PBMC layer | No                        | No   | No                                    | Deviation not due to human error                            |   |
| CV01EM009  | 100 µg (18-55 years) | 1                | Too few aliquots obtained           | Protocol procedure /assessment | 1         | Other: Poor quality PBMC layer | No                        | No   | No                                    | Deviation not due to human error                            |   |
| CV01EM009  | 100 µg (18-55 years) | 2                | Required procedure done incorrectly | Protocol procedure /assessment | 55        | Clinic error                   | No                        | No   | No                                    | Remind staff to double check the amount of blood collected. |   |
| CV01EM010  | 100 µg (18-55 years) | 1                | Too few aliquots obtained           | Protocol procedure /assessment | 1         | Other: Poor quality PBMC layer | No                        | No   | No                                    | Deviation not due to human error                            |   |
| CV01EM012  | 100 µg (18-55 years) | 1                | Too few aliquots obtained           | Protocol procedure /assessment | 1         | Laboratory error               | No                        | No   | No                                    | Rinse more CPT tubes to collect buffy coat layer            | Suspected that entire buffy coat wasn't collected |
| CV01EM016  | 250 µg (18-55 years) | 1                | Too few aliquots obtained           | Protocol procedure /assessment | 1         | Other: poor quality PBMC layer | No                        | No   | No                                    | Deviation not due to human error                            |   |
| CV01EM016  | 250 µg (18-55 years) | 2                | Too few aliquots obtained           | Protocol procedure /assessment | 56        | Other: Poor quality PBMC layer | No                        | No   | No                                    | Deviation not due to human error                            |   |
| CV01EM016  | 250 µg (18-55 years) | 3                | Too few aliquots obtained           | Protocol procedure /assessment | 116       | Other: Poor quality PBMC layer | No                        | No   | No                                    | Deviation not due to human error                            |   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix G1 (continued)**  
**Listing of Protocol Deviations**

| Subject ID | Vaccination Group    | Deviation Number | Deviation                        | Deviation Category             | Study Day | Reason for Deviation  | Deviation Resulted in AE? | Deviation Resulted in Subject Termination? | Deviation Affected Product Stability? | Deviation Resolution   | Comments  |
|------------|----------------------|------------------|----------------------------------|--------------------------------|-----------|---|---------------------------|--|---------------------------------------|--|---|
| CV01EM027  | 25 µg (56-70 years)  | 1                | Too few aliquots obtained        | Protocol procedure /assessment | 1         | Other: Poor quality PBMC layer                                  | No                        | No   | No                                    | Deviation not due to human error                                   | Protocol deviation originally written on version 2.0. Updated to version 3.0.   |
| CV01EM030  | 25 µg (56-70 years)  | 1                | Too few aliquots obtained        | Protocol procedure /assessment | 58        | Other: Poor quality PBMC layer. A lot of red cell contamination | No                        | No   | No                                    | Deviation not due to human error                                   |   |
| CV01EM039  | 100 µg (56-70 years) | 1                | Missed visit/visit not conducted | Follow-up visit schedule       | 2         | Subject unable to comply  | No                        | No   | No                                    | Explained the importance of completing study visits to the subject | Once contact was made with the subject, the importance of completing each study visit within the time frame was reiterated and subject responded with an understanding. |
| CV01EM051  | 50 µg (18-55 years)  | 1                | Out of window visit              | Follow-up visit schedule       | 62        | Subject illness   | No                        | No   | No                                    | unavoidable  |   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix G1 (continued)**  
**Listing of Protocol Deviations**

| Subject ID | Vaccination Group    | Deviation Number | Deviation                           | Deviation Category             | Study Day | Reason for Deviation     | Deviation Resulted in AE? | Deviation Resulted in Subject Termination? | Deviation Affected Product Stability? | Deviation Resolution  | Comments |
|------------|----------------------|------------------|-------------------------------------|--------------------------------|-----------|--------------------------|---------------------------|--|---------------------------------------|---|----------|
| CV01HC003  | 100 µg (18-55 years) | 1                | Out of window visit                 | Follow-up visit schedule       | 46        | Subject refusal          | No                        | No   | No                                    | subjects will be reminded of importance of attending study visits within window |          |
| CV01HC003  | 100 µg (18-55 years) | 2                | Required procedure done incorrectly | Protocol procedure /assessment | 46        | Subject refusal          | No                        | No   | No                                    | subject moved out of state unexpectedly   |          |
| CV01HC003  | 100 µg (18-55 years) | 3                | Required procedure done incorrectly | Protocol procedure /assessment | 55        | Subject refusal          | No                        | No   | No                                    | subject moved out of state unexpectedly   |          |
| CV01HC003  | 100 µg (18-55 years) | 4                | Out of window visit                 | Follow-up visit schedule       | 127       | Subject unable to comply | No                        | No   | No                                    | subject reminded of importance of visit windows                                 |          |
| CV01HC012  | 250 µg (18-55 years) | 1                | Required procedure not conducted    | Protocol procedure /assessment | 7         | Clinic error             | Yes, unsolicited AE       | No   | No                                    | Coordinator re-trained on the importance of performing required procedures      |          |
| CV01HC027  | 25 µg (56-70 years)  | 1                | Out of window visit                 | Follow-up visit schedule       | 61        | Subject unable to comply | No                        | No   | N/A                                   | explained to subject the importance of remaining compliant with study protocol. |          |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix G1 (continued)**  
**Listing of Protocol Deviations**

| Subject ID | Vaccination Group   | Deviation Number | Deviation                               | Deviation Category             | Study Day | Reason for Deviation     | Deviation Resulted in AE? | Deviation Resulted in Subject Termination? | Deviation Affected Product Stability? | Deviation Resolution   | Comments   |
|------------|---------------------|------------------|---|--------------------------------|-----------|--------------------------|---------------------------|--|---------------------------------------|--|--|
| CV01HC048  | 50 µg (18-55 years) | 1                | Required procedure done incorrectly     | Protocol procedure /assessment | 44        | Subject unable to comply | No                        | No   | No                                    | subject reminded of visit schedule   |  |
| CV01KP001  | 25 µg (18-55 years) | 1                | Other: non-required lab tests performed | Protocol procedure /assessment | 1         | Laboratory error         | No                        | No   | N/A                                   | staff instructed to review study requirements and lab form prior to submission           | lab staff did not fill out requisition form properly, so complete CBC was done rather than only study required tests.  |
| CV01KP010  | 25 µg (18-55 years) | 1                | Required procedure done incorrectly     | Protocol procedure /assessment | -14       | Laboratory error         | No                        | No   | No                                    | Lab staff will prepare tubes prior to study visit and double-check tubes again post-draw | Incorrect tube size was used during specimen collection. As a preventative measure, lab staff will prepare blood collection tubes prior to study visits and double-check again post-draw to confirm correct tubes were used. |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020



**Appendix G1 (continued)**  
**Listing of Protocol Deviations**

| Subject ID | Vaccination Group    | Deviation Number | Deviation                                     | Deviation Category                | Study Day | Reason for Deviation         | Deviation Resulted in AE? | Deviation Resulted in Subject Termination? | Deviation Affected Product Stability? | Deviation Resolution   | Comments   |
|------------|----------------------|------------------|---|-----------------------------------|-----------|------------------------------|---------------------------|--|---------------------------------------|--|--|
| CV01KP012  | 100 µg (18-55 years) | 1                | Other: breach of confidentiality              | Protocol procedure /assessment    | -4        | Clinic error                 | No                        | No   | N/A                                   | retraining of study staff  | subject name was included on Quest requisition form, rather than study ID. |
| CV01KP018  | 25 µg (18-55 years)  | 1                | Required procedure not conducted              | Protocol procedure /assessment    | 8         | Investigator /study decision | No                        | No   | N/A                                   | Pt. under quarantine due to exposure, required procedures will be completed at V5                  |  |
| CV01KP018  | 25 µg (18-55 years)  | 2                | Other: V4 safety labs collected out of window | Protocol procedure /assessment    | 17        | Subject unable to comply     | No                        | No   | N/A                                   | Pt. unable to comply due to quarantine. V4 safety labs drawn at V5                                 |  |
| CV01KP037  | 250 µg (18-55 years) | 1                | Required procedure done incorrectly           | Treatment administration schedule | 28        | Subject illness              | No                        | No   | No                                    | Will continue to attempt to complete visits per protocol   |  |
| CV01KP048  | 250 µg (18-55 years) | 1                | Required procedure done incorrectly           | Protocol procedure /assessment    | 1         | Laboratory error             | No                        | No   | N/A                                   | Lab staff will use a timer for visits requiring safety labs due to their shorter clot time window. |  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix G1 (continued)**  
**Listing of Protocol Deviations**

| Subject ID | Vaccination Group    | Deviation Number | Deviation                           | Deviation Category             | Study Day | Reason for Deviation | Deviation Resulted in AE? | Deviation Resulted in Subject Termination? | Deviation Affected Product Stability? | Deviation Resolution  | Comments   |
|------------|----------------------|------------------|-------------------------------------|--------------------------------|-----------|----------------------|---------------------------|--|---------------------------------------|---|--|
| CV01KP049  | 250 µg (18-55 years) | 1                | Required procedure done incorrectly | Protocol procedure /assessment | 113       | Clinic error         | No                        | No   | N/A                                   | Retrained staff on importance of reviewing required procedures at the end of clinic visits. | Temperature not taken in clinic at V12 on 03Aug2020. Participant reached at home same day. Reported temp 97.6 degrees F @ 09:55. |
| CV01KP060  | 25 µg (≥71 years)    | 1                | Too few aliquots obtained           | Protocol procedure /assessment | 113       | Clinic error         | No                        | No   | N/A                                   | Discussed with staff importance of obtaining all required blood samples at each visit.      |  |
| CV01KP071  | 100 µg (≥71 years)   | 1                | Too few aliquots obtained           | Protocol procedure /assessment | 56        | Clinic error         | No                        | No   | N/A                                   | Retrained staff on inventory management to ensure adequate supply of tubes                  | Low availability of CPT tubes resulted in 1 tube drawn for PBMCs instead of 2 at V11.  |
| CV01KP076  | 100 µg (≥71 years)   | 1                | Too few aliquots obtained           | Protocol procedure /assessment | 56        | Clinic error         | No                        | No   | N/A                                   | Retrained staff on inventory management to ensure adequate supply of tubes                  | Low availability of CPT tubes at clinic resulted in 1 CPT tube drawn for PBMCs at V11 instead of 2.                              |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**Appendix G1 (continued)**  
**Listing of Protocol Deviations**

| Subject ID | Vaccination Group   | Deviation Number | Deviation                           | Deviation Category             | Study Day | Reason for Deviation     | Deviation Resulted in AE? | Deviation Resulted in Subject Termination? | Deviation Affected Product Stability? | Deviation Resolution                                       | Comments  |
|------------|---------------------|------------------|-------------------------------------|--------------------------------|-----------|--------------------------|---------------------------|--|---------------------------------------|--|---|
| CV01KP085  | 100 µg (≥71 years)  | 1                | Specimen result not obtained        | Protocol procedure /assessment | 29        | Laboratory error         | No                        | No   | N/A                                   | unavoidable  | Lab unable to report due to significant platelet clumping |
| CV01KP095  | 50 µg (18-55 years) | 1                | Required procedure done incorrectly | Protocol procedure /assessment | 34        | Laboratory error         | No                        | No   | N/A                                   | Lab staff will use timers for all visits.                  |   |
| CV01KP096  | 50 µg (18-55 years) | 1                | Out of window visit                 | Follow-up visit schedule       | 36        | Subject unable to comply | No                        | No   | N/A                                   | Discussed with subject the importance of scheduled visits. |   |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**APPENDIX G2:  
Listing of Non-Subject Deviations**

| Study Site              | Deviation Number | Deviation  | Deviation Category            | Reason for Deviation                                      | Deviation Affected Product Stability? | Deviation Resolution  |
|-------------------------|------------------|--|-------------------------------|---|---------------------------------------|---|
| Vaccine Research Center | 1                | Other: Personal Identifying Information disclosure | Protocol procedure/assessment | Other:Medical Secure Email Information Technology Problem | No                                    | Email packet deleted, Effected subjects contacted, Information Technology dept. investigation ongoing, team will not use this system for group blind cc email distribution in future. |
| Emory Children's Center | 1                | Study product temperature excursion                | Protocol procedure/assessment | Other:EUC -80 freezer had a malfunction.                  | Yes                                   | A new -80 freezer has been purchased and in use.  |

| Study Site              | Deviation Number | Comments  |
|-------------------------|------------------|---|
| Vaccine Research Center | 1                | We are reporting an Unanticipated Problem of inadvertent disclosure of study participation by one subject to other study subjects via email. The UP occurred after a medically secured email sent by a study team member was used in “reply all” fashion and four trial participants inadvertently disclosed their names and email addresses to each other on June 11th, 2020. We are reporting this event as a UP because it was unexpected, related to study participation, and is a potential social risk to participants in that others became aware that they screened for a research study. We do not believe any actual material harm has occurred for participants due to this disclosure. DMID 20-0003 study participants were blind carbon copied (BCC) on a study status update email sent through a medically secure email server operated by the NIH Clinical Center. Prior to sending the email, the study team sought confirmation with the NIH Medical Records Department that this was an appropriate means of communication and would not result in disclosure of study participant’s identification. The Medical Records Department confirmed that this email would not provide study participants with access to others’ identification. Due to an IT glitch, however, a participant who screened but did not ultimately enroll in the study replied all to the email thread and included his name and information about his screening status. This email was then seen by 9 other participants on study. No other information including medical history were disclosed. Two other subjects who screened for the study and 1 who enrolled replied to the email thread indicated they believed they were included on the message in error. Their names were also disclosed as having screened for the study, however, no other information including medical history were disclosed. All subjects whose names were disclosed and who opened the email have been notified of the event and that we are reporting the event as an Unanticipated Problem. |
| Emory Children's Center | 1                | The affected study product was immediately removed from EUC -80 freezer to EUH -80 freezer on April 17, 2020. The excursion was reported to DMID on April 18, 2020. DMID instructed to continue to use IP.  |

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020

**APPENDIX H:  
Listing of Pregnancies**

**Table 1 – Maternal Information**

**No maternal information has been reported**

**Table 2 – Gravida and Para**

**No gravida and para have been reported.**

**Table 3 – Live Birth Outcomes**

**No live birth outcomes have been reported**

**Table 4 – Still Birth Outcomes**

**No still birth outcomes have been reported**

**Table 5 – Spontaneous, Elective, or Therapeutic Abortion Outcomes**

**No spontaneous, elective, or therapeutic abortion outcomes have been reported**

Report Date: 26OCT2020  
Data Cutoff Date: 07OCT2020