

|                      |         |
|----------------------|---------|
| Mfr Report #         | (b) (6) |
| UF/Importer Report # |         |
| FDA Use Only         |         |

|                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                        |                                                                                       |                                          |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|---------------------------------------------------------------------------------------|------------------------------------------|
| <b>A. PATIENT INFORMATION</b>                                                                                                                                                                                                                                                                                                                                                                                             |                                                                        |                                                                                       |                                          |
| 1. Patient Identifier<br>US2081123                                                                                                                                                                                                                                                                                                                                                                                        | 2. Age at Time of Event: 65 Years<br>or<br>Date of Birth: (b) (6)/1954 | 3. Sex<br><input type="checkbox"/> Female<br><input checked="" type="checkbox"/> Male | 4. Weight<br>184.8 lbs<br>or<br>83.8 kgs |
| In confidence                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                        |                                                                                       |                                          |
| <b>B. ADVERSE EVENT OR PRODUCT PROBLEM</b>                                                                                                                                                                                                                                                                                                                                                                                |                                                                        |                                                                                       |                                          |
| 1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product Problem (e.g., defects/malfunctions)                                                                                                                                                                                                                                                                                         |                                                                        |                                                                                       |                                          |
| 2. Outcomes Attributed to Adverse Event<br>(Check all that apply)                                                                                                                                                                                                                                                                                                                                                         |                                                                        |                                                                                       |                                          |
| <input type="checkbox"/> Death: (mm/dd/yyyy) <input type="checkbox"/> Disability or Permanent Damage                                                                                                                                                                                                                                                                                                                      |                                                                        |                                                                                       |                                          |
| <input checked="" type="checkbox"/> Life-threatening <input type="checkbox"/> Congenital Anomaly/Birth Defect                                                                                                                                                                                                                                                                                                             |                                                                        |                                                                                       |                                          |
| <input checked="" type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Other Serious (Important Medical Events)                                                                                                                                                                                                                                                                              |                                                                        |                                                                                       |                                          |
| <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage (Devices)                                                                                                                                                                                                                                                                                                                           |                                                                        |                                                                                       |                                          |
| 3. Date of Event (mm/dd/yyyy)<br>08/01/2020                                                                                                                                                                                                                                                                                                                                                                               |                                                                        | 4. Date of This Report (mm/dd/yyyy)<br>12/06/2020                                     |                                          |
| 5. Describe Event or Problem<br>Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)<br>Double pneumonia (community acquired) [Community acquired pneumonia]                                                                                                                                                                                                                                   |                                                                        |                                                                                       |                                          |
| Case Description:<br>This 65-year-old, White, male subject (US2081123) was participating in A Phase 2, Randomized, Observer-Blind, Placebo-Controlled, Dose-Finding Trial to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older (mRNA-1273-P201), and experienced double pneumonia (community acquired).                                           |                                                                        |                                                                                       |                                          |
| The subject's medical history, as provided by the investigator, included osteoarthritis of lower back, erectile dysfunction, spinal stenosis, attention deficit/hyperactivity continued in additional info section...                                                                                                                                                                                                     |                                                                        |                                                                                       |                                          |
| 6. Relevant Tests/Laboratory Data, Including Dates<br>#1 08/01/2020 Basophil count (continued)<br>#2 08/11/2020 Blood alkaline phosphatase (continued)<br>#3 08/17/2020 Blood alkaline phosphatase (continued)<br>#4 08/24/2020 Blood alkaline phosphatase (continued)<br>#5 08/17/2020 Blood creatine phosphokinase (continued)<br>#6 08/17/2020 Blood creatinine (continued)<br>continued in additional info section... |                                                                        |                                                                                       |                                          |
| 7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)<br>Race: White<br>#1 --/--/2000 to Ongoing Current Condition, (Continued)<br>#2 --/--/2000 to Ongoing Current Condition, (Continued)<br>#3 --/--/2003 to Ongoing Current Condition, (Continued)<br>continued in additional info section...                |                                                                        |                                                                                       |                                          |

|                                                                                                                                                                                       |              |                                                                                                                                                                                                |  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| <b>C. SUSPECT PRODUCT(S)</b>                                                                                                                                                          |              |                                                                                                                                                                                                |  |
| 1. Name (Give labeled strength & mfr/labeler)                                                                                                                                         |              |                                                                                                                                                                                                |  |
| #1. mRNA-1273 vs Placebo (Code not broken)                                                                                                                                            |              |                                                                                                                                                                                                |  |
| #2.                                                                                                                                                                                   |              |                                                                                                                                                                                                |  |
| 2. Dose, Frequency & Route Used                                                                                                                                                       |              | 3. Therapy Dates (if unknown, give duration) from/to (or best estimate)                                                                                                                        |  |
| #1. Blinded, Information withheld.                                                                                                                                                    |              | #1. 06/30/2020 to 06/30/2020                                                                                                                                                                   |  |
| #2.                                                                                                                                                                                   |              | #2.                                                                                                                                                                                            |  |
| 4. Diagnosis for Use (Indication)                                                                                                                                                     |              | 5. Event Abated After Use Stopped or Dose Reduced?                                                                                                                                             |  |
| #1. COVID-19 (Continued)                                                                                                                                                              |              | #1. <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply                                                                                 |  |
| #2.                                                                                                                                                                                   |              | #2. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply                                                                                            |  |
| 6. Lot #                                                                                                                                                                              | 7. Exp. Date | 8. Event Reappeared After Reintroduction?                                                                                                                                                      |  |
| #1. Blinded                                                                                                                                                                           | #1. Blinded  | #1. <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply                                                                                 |  |
| #2.                                                                                                                                                                                   | #2.          | #2. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply                                                                                            |  |
| 9. NDC# or Unique ID                                                                                                                                                                  |              |                                                                                                                                                                                                |  |
| 10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)<br>1) METHYLPHENIDATE (METHYLPHENIDATE) 03/--/2020 to ongoing continued in additional info section... |              |                                                                                                                                                                                                |  |
| <b>G. ALL MANUFACTURERS</b>                                                                                                                                                           |              |                                                                                                                                                                                                |  |
| 1. Contact Office (and Manufacturing Site for Devices)                                                                                                                                |              | 2. Phone Number                                                                                                                                                                                |  |
| Name<br>ModernaTX, Inc. David Martin MD.                                                                                                                                              |              | 617-335-1804                                                                                                                                                                                   |  |
| Address<br>200 Technology Square<br>Cambridge, MA 02139<br>United States of America                                                                                                   |              | 3. Report Source (Check all that apply)                                                                                                                                                        |  |
| Email Address                                                                                                                                                                         |              | <input type="checkbox"/> Foreign                                                                                                                                                               |  |
|                                                                                                                                                                                       |              | <input checked="" type="checkbox"/> Study                                                                                                                                                      |  |
|                                                                                                                                                                                       |              | <input type="checkbox"/> Literature                                                                                                                                                            |  |
|                                                                                                                                                                                       |              | <input type="checkbox"/> Consumer                                                                                                                                                              |  |
|                                                                                                                                                                                       |              | <input checked="" type="checkbox"/> Health Professional                                                                                                                                        |  |
|                                                                                                                                                                                       |              | <input type="checkbox"/> User Facility                                                                                                                                                         |  |
|                                                                                                                                                                                       |              | <input type="checkbox"/> Company Representative                                                                                                                                                |  |
|                                                                                                                                                                                       |              | <input type="checkbox"/> Distributor                                                                                                                                                           |  |
|                                                                                                                                                                                       |              | <input type="checkbox"/> Other:                                                                                                                                                                |  |
| 4. Date Received by Manufacturer (mm/dd/yyyy)<br>10/02/2020                                                                                                                           |              | 5. (A)NDA #<br>IND # 019635<br>BLA #<br>PMA/ 510(k) #<br>Combination Product <input type="checkbox"/> Yes<br>Pre-1938 <input type="checkbox"/> Yes<br>OTC Product <input type="checkbox"/> Yes |  |
| 6. If IND, Give Protocol #<br>mRNA-1273-P201                                                                                                                                          |              |                                                                                                                                                                                                |  |
| 7. Type of Report (Check all that apply)                                                                                                                                              |              |                                                                                                                                                                                                |  |
| <input type="checkbox"/> 5-day <input type="checkbox"/> 30-day                                                                                                                        |              |                                                                                                                                                                                                |  |
| <input type="checkbox"/> 7-day <input type="checkbox"/> Periodic                                                                                                                      |              |                                                                                                                                                                                                |  |
| <input type="checkbox"/> 10-day <input type="checkbox"/> Initial                                                                                                                      |              |                                                                                                                                                                                                |  |
| <input type="checkbox"/> 15-day <input checked="" type="checkbox"/> Follow-up #7                                                                                                      |              |                                                                                                                                                                                                |  |
| 9. Manufacturer Report Number<br>(b) (6)                                                                                                                                              |              | 8. Adverse Event Term(s)<br>Community acquired pneumonia                                                                                                                                       |  |
| <b>E. INITIAL REPORTER</b>                                                                                                                                                            |              |                                                                                                                                                                                                |  |
| 1. Name and Address<br>Dr. Barton Williams<br>Trial Management Associates<br>3806 Peachtree Avenue, Suite 200 Wilmington, NC 28403 UNITED STATES                                      |              |                                                                                                                                                                                                |  |
| Phone #<br>(b) (6)                                                                                                                                                                    |              | Email Address<br>(b) (6) @trialmgt.com                                                                                                                                                         |  |
| 2. Health Professional?<br><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No                                                                                        |              | 3. Occupation<br>Physician                                                                                                                                                                     |  |
|                                                                                                                                                                                       |              | 4. Initial Reporter Also Sent Report to FDA<br><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unk                                                |  |

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event

**ADDITIONAL INFORMATION****B5. EVENT DESCRIPTION (Continued)**

disorder, depression, and was a non-smoker. Concomitant medications reported included methylphenidate, duloxetine hydrochloride, and multivitamin.

The subject was allocated to receive intramuscular mRNA-1273 or placebo for SARS-CoV-2 vaccination. The subject received the first dose of study drug on 30 Jun 2020. There were no additional doses administered prior to event onset.

On 25 Jul 2020, the subject was seen in the office by the primary investigator for symptoms of headache, cough, body aches all over, weakness and fever. He was tested via nasal swab for COVID-19. Oral acetaminophen and oral ibuprofen were given for pain associated with bilateral pneumonia.

On 29 Jul 2020, the subject attended an unscheduled site visit due to not feeling well and continued to experience the above-mentioned symptoms. The study medication dose was delayed. Vital signs included blood pressure (BP) 114/64 mmHg, oral temperature 99.8 degrees Fahrenheit, heart rate 68 beats per minute and respiratory rate 19 breaths per minute. A non-diagnostic chest x-ray revealed possible pneumonia. On that same day, the results from the COVID-19 test performed on 25 Jul 2020 came back negative. A second nasal swab for COVID-19 was negative, and a complete blood count was collected.

On 01 Aug 2020, the subject went to the emergency room (ER) with worsening symptoms including cough with some productive sputum, elevated fevers, urinary issues, body aches, joint pains, and generalized weakness. He presented to the ER with increased ongoing confusion for two days and reported being sick for 10 days. Physical exam revealed that he was alert and oriented to person, place and time; however, he appeared distressed, somewhat confused with altered mental status. His breathing was normal, without wheezing rhonchi or respiratory distress. Vital signs included body temperature 97.8 degrees Fahrenheit, BP 116/96 mmHg, pulse 67 beats per minute, 21 breaths per minute, and oxygen saturation 95%. Laboratory results included white blood cell count (WBC) 13.4 K/uL (4.0-10.0), absolute lymphocytes 0.94 K/uL (1.20-3.70), absolute monocytes 0.94 K/uL (0.20-0.80), absolute basophils 0.13 K/uL (0.00-0.10), red blood cell count (RBC) 3.52 M/uL (4.63-6.08), hemoglobin (HGB) 11.0 g/dL (13.7-17.5), and hematocrit (HCT) 33.7 % (40.1-51.0). Urinalysis and blood cultures were negative. A nasopharyngeal rapid polymerase chain reaction for SARS-CoV-2 was negative. A chest x-ray revealed bilateral heterogeneous pulmonary opacities, with the right side being greater than the left side, without effusions, which was suggestive of a bilateral atypical infection. An electrocardiogram revealed mild bradycardia. Due to leukocytosis with bandemia and chest x-ray results, the subject was considered to be septic secondary to the life-threatening event of double pneumonia (community acquired) and was hospitalized. Treatment for pneumonia included a five-day course of intravenous (IV) azithromycin and ceftriaxone, with a bolus of IV fluids. The subject was also treated with oral loperamide for diarrhea related to pneumonia. The subject's BP as reassessment revealed systolic was 98 mmHg. Additional IV fluids were administered with noted improvement in BP.

On 02 Aug 2020, blood cultures were drawn, and were negative for growth after 2 days. Glucose was 114 mg/dL (74-106).

On 03 Aug 2020, laboratory results included WBC 11.1 K/uL, RBC 3.15 M/uL, HGB 10.1 g/dL, and HCT 29.8 %.

On 04 Aug 2020, the subject was treated with butalbital-acetaminophen-caffeine for tension headaches related to pneumonia.

On 05 Aug 2020, vital signs included BP 107/51 mmHg, pulse 48 beats per minute, body temperature 98.6 degrees Fahrenheit, respiratory rate 17 breaths per minute, and oxygen saturation 94%. Physical exam revealed bilateral diminished breath sounds without respiratory distress. Laboratory results included WBC 12.6 K/uL, RBC 3.27 M/uL, HGB 10.3 g/dL, HCT 31.4 %, absolute neutrophils 9.90 K/uL (1.60-6.10), absolute lymphocytes 1.06 K/uL, absolute monocytes 0.90 K/uL and absolute immature granulocytes 0.46 K/uL (0.00-0.03). Blood cultures remained negative. On that same day, the subject was discharged from the hospital in stable condition. The subject was prescribed a seven day course of oral levofloxacin for sepsis related to pneumonia, and oral guaifenesin and benzonatate for pneumonia. The subject was advised to follow-up with his primary care physician for transition care in one week and to schedule a repeat x-ray in four to six weeks to ensure resolution of pneumonia.

On 11 Aug 2020, at study visit 4, day 29, central laboratory results included platelet count 901 thousand/uL (140-400) and alkaline phosphatase (ALP) 477 U/L (35-144) revealed elevated platelet count and elevated alkaline phosphatase.

On 17 Aug 2020, local laboratory revealed gamma-glutamyl transferase (GGT) 244 U/L (3-70), ALP 249 U/L, creatinine kinase 41 U/L (44-196), urea nitrogen 29 mg/dL (7-25), creatinine 0.69 mg/dL (0.70-1.25), RBC 3.79 million/uL (4.20-5.80), HGB 12.1 g/dL (13.2-17.1), HCT 37.0% (38.5-50.0), platelet count (PLT) 618 thousand/uL, Epstein Barr viral (EBV) capsid antigen antibody (IGG) 508 U/mL (high), EBV capsid antigen antibody (IGM) <30 U/mL. EBV nuclear antigen antibody (IGG) 46.8 U/mL (high), and a negative cytomegalovirus antibody IGG and IGM. Both EBV results were consistent with prior, but not recent, exposure.

On 19 Aug 2020, a right upper quadrant ultrasound revealed borderline hepatomegaly with increased echogenicity likely due to fatty replacement; no focal intrahepatic lesions were seen; gallbladder sludge layering dependently in the gallbladder; no definite calculi, wall thickening or pericholecystic fluid seen; normal bile ducts; and mild aortic ectasia with maximum dimension of 34 millimeters in the proximal segment.

On 20 Aug 2020, a two view chest x-ray revealed persistent right lower lobe airspace disease compatible with pneumonia, slightly decreased from prior study.

On 24 Aug 2020, laboratory results revealed GGT 155 U/L, creatinine 0.68 mg/dL, ALP 160 U/L, RBC 3.91 million/uL, HGB 12.3 g/dL, HCT 38.1% and PLT 311 thousand/uL.

On 26 Aug 2020, the subject was seen in follow-up via virtual visit with primary provider for abnormal laboratory results. At this time, platelet count was within normal limits, elevated ALP had fallen from 477 U/L to 160 U/L and was almost back to normal and GGT had decreased from 244 U/L to 155 U/L. Aspartate aminotransferase, alanine aminotransferase, and bilirubin were normal throughout. The subject reported feeling back to baseline, and the weakness and fatigue had resolved. He had started an exercise program and reported doing well. He was educated to report any new or unusual symptoms and to return to clinic for follow-up in two months.

Study drug was discontinued per primary investigator and sponsor review in response to the event, with the last dose administered on 30 Jun 2020.

The event, double pneumonia (community acquired), was considered resolved on 26 Aug 2020.

The investigator assessed the event, double pneumonia (community acquired), as not related to study drug or study procedure.

Follow-up received on 04 Aug 2020 and 06 Aug 2020 included hospital records, medical history, laboratory results, diagnostic test results, treatment, action taken with study drug, diagnosis and course of event details.

Follow-up received on 17 Aug 2020, 19 Aug 2020 and 20 Aug 2020 included updated event term, additional seriousness criteria, hospital discharge records, testing, treatment, and course of hospitalization.

Follow-up received on 27 Aug 2020 and 28 Aug 2020 included updated event verbatim, additional treatment medications and laboratory results.

Follow-up received on 02 Sep 2020 included additional laboratory results, diagnostic results, and event details obtained from medical records.

Follow-up received on 09 Sep 2020 and 11 Sep 2020 included event details, end date and updated outcome.

Follow-up received on 18 Sep 2020 included no new information.

Follow-up received on 02 Oct 2020 included amended treatment medication.

Follow-up received on 22 Oct 2020 included no new information.

Follow-up received on 02 Nov 2020 included no new information.

## Case Comment/Sender's Comment:

Company Comment: This case concerns a 65-year-old subject with a medical history of osteoarthritis of lower back, spinal stenosis, attention deficit/hyperactivity disorder, depression, and was a non-smoker, who experienced an unexpected event of Grade IV community acquired double pneumonia. The subject's clinical course included pneumonia related sepsis and elevated alkaline phosphatase and GGT, and reactive thrombocytosis (the distinction may be relevant to the diagnosis without AST, ALT or bilirubin elevation). The event occurred 25 days after study vaccination. The event was considered unrelated to the study vaccine in agreement with the Investigator's assessment.

## B6. LABORATORY DATA

| # | Date       | Test / Assessment / Notes | Results                 | Normal High / Low |
|---|------------|---------------------------|-------------------------|-------------------|
| 1 | 08/01/2020 | Basophil count            | 0.13 10 <sup>9</sup> /L | 0.10              |

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|    |            |                                                                                                                                                                                                                                           |             |              |
|----|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|--------------|
| 2  | 08/11/2020 | Blood alkaline phosphatase                                                                                                                                                                                                                | 477 U/L     | 144<br>35    |
| 3  | 08/17/2020 | Blood alkaline phosphatase                                                                                                                                                                                                                | 249 U/L     | 144<br>35    |
| 4  | 08/24/2020 | Blood alkaline phosphatase                                                                                                                                                                                                                | 160 U/L     | 144<br>35    |
| 5  | 08/17/2020 | Blood creatine phosphokinase                                                                                                                                                                                                              | 41 U/L      | 196<br>44    |
| 6  | 08/17/2020 | Blood creatinine                                                                                                                                                                                                                          | 0.69 mg/dl  | 1.25<br>0.70 |
| 7  | 08/24/2020 | Blood creatinine                                                                                                                                                                                                                          | 0.68 mg/dl  | 1.25<br>0.70 |
| 8  | 08/01/2020 | Blood culture<br>Negative                                                                                                                                                                                                                 | negative    |              |
| 9  | 08/02/2020 | Blood culture<br>Negative<br>No growth after 2 days                                                                                                                                                                                       | negative    |              |
| 10 | 08/02/2020 | Blood glucose                                                                                                                                                                                                                             | 114 mg/dl   | 106<br>74    |
| 11 | 07/29/2020 | Blood pressure measurement                                                                                                                                                                                                                | 114/64 mmHg |              |
| 12 | 08/01/2020 | Blood pressure measurement                                                                                                                                                                                                                | 116/96 mmHg |              |
| 13 | 08/05/2020 | Blood pressure measurement                                                                                                                                                                                                                | 107/51 mmHg |              |
| 14 | 08/01/2020 | Blood pressure systolic                                                                                                                                                                                                                   | 98 mmHg     |              |
| 15 | 08/17/2020 | Blood urea                                                                                                                                                                                                                                | 29 mg/dl    | 25<br>7      |
| 16 | 07/29/2020 | Body temperature                                                                                                                                                                                                                          | 99.8 °F     |              |
| 17 | 08/01/2020 | Body temperature                                                                                                                                                                                                                          | 97.8 °F     |              |
| 18 | 08/05/2020 | Body temperature                                                                                                                                                                                                                          | 98.6 °F     |              |
| 19 | 07/29/2020 | Chest X-ray<br>normal<br>Non-diagnostic                                                                                                                                                                                                   |             |              |
| 20 | 08/01/2020 | Chest X-ray<br><br>Compared to results from 21 Jun 2016, revealed bilateral heterogeneous pulmonary opacities, with the right side being greater than the left side, without effusions, was suggestive of a bilateral atypical infection. |             |              |
| 21 | 08/20/2020 | Chest X-ray<br><br>Persistent right lower lobe airspace disease compatible with pneumonia, slightly decreased from prior study.                                                                                                           |             |              |
| 22 | 08/17/2020 | Cytomegalovirus test<br>Negative<br>IgG and IgM                                                                                                                                                                                           |             |              |

|    |            |                                                                                                                                                                                   |                         |                            |
|----|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------------|
| 23 | 08/01/2020 | Electrocardiogram                                                                                                                                                                 |                         |                            |
|    |            | Mild bradycardia                                                                                                                                                                  |                         |                            |
| 24 | 08/17/2020 | Epstein-Barr virus antibody                                                                                                                                                       |                         |                            |
|    |            | EBV viral CAPSID AG (VCA) AB (IGG) 508.00 (high); EBV capsid antigen antibody (IGM) <30 U/ml; EBV nuclear AG (EBNA) AB (IGG) 46.80 (high); Consistent prior, but recent, exposure |                         |                            |
| 25 | 08/17/2020 | Gamma-glutamyltransferase                                                                                                                                                         | 244 U/L                 | 70<br>3                    |
| 26 | 08/24/2020 | Gamma-glutamyltransferase                                                                                                                                                         | 155 U/L                 | 70<br>3                    |
| 27 | 08/05/2020 | Granulocyte count<br>High                                                                                                                                                         | 0.46 10 <sup>9</sup> /L | 0.03<br>0.00               |
| 28 | 08/01/2020 | Haematocrit                                                                                                                                                                       | 33.7 percent            | 51.0<br>40.1               |
| 29 | 08/03/2020 | Haematocrit                                                                                                                                                                       | 29.8 percent            | 51.0<br>40.1               |
| 30 | 08/05/2020 | Haematocrit                                                                                                                                                                       | 31.4 percent            | 51.0<br>40.1               |
| 31 | 08/17/2020 | Haematocrit                                                                                                                                                                       | 37.0 percent            | 50.0<br>38.5               |
| 32 | 08/24/2020 | Haematocrit                                                                                                                                                                       | 38.1 percent            | 50.0<br>38.5               |
| 33 | 08/01/2020 | Haemoglobin                                                                                                                                                                       | 11.0 g/dL               | 17.5<br>13.7               |
| 34 | 08/03/2020 | Haemoglobin                                                                                                                                                                       | 10.1 g/dL               | 17.5<br>13.7               |
| 35 | 08/05/2020 | Haemoglobin                                                                                                                                                                       | 10.3 g/dL               | 17.5<br>13.7               |
| 36 | 08/17/2020 | Haemoglobin                                                                                                                                                                       | 12.1 g/dL               | 17.1<br>13.2               |
| 37 | 08/24/2020 | Haemoglobin                                                                                                                                                                       | 12.3 g/dL               | 17.1<br>13.2               |
| 38 | 07/29/2020 | Heart rate                                                                                                                                                                        | 68 /min                 |                            |
| 39 | 08/01/2020 | Heart rate                                                                                                                                                                        | 67 /min                 |                            |
| 40 | 08/05/2020 | Heart rate                                                                                                                                                                        | 48 /min                 |                            |
| 41 | 08/01/2020 | Lymphocyte count                                                                                                                                                                  | 0.94 10 <sup>9</sup> /L | 3.70<br>1.20               |
| 42 | 08/05/2020 | Lymphocyte count                                                                                                                                                                  | 1.06 10 <sup>9</sup> /L | 3.70<br>1.20               |
| 43 | 08/01/2020 | Monocyte count                                                                                                                                                                    | 0.94 10 <sup>9</sup> /L | 0.80<br>0.20               |
| 44 | 08/05/2020 | Monocyte count                                                                                                                                                                    | 0.90 10 <sup>9</sup> /L | 0.80<br>0.20               |
| 45 | 08/05/2020 | Neutrophil count                                                                                                                                                                  | 9.90 10 <sup>9</sup> /L | 6.10<br>1.60               |
| 46 | 08/01/2020 | Oxygen saturation                                                                                                                                                                 | 95 percent              |                            |
| 47 | 08/05/2020 | Oxygen saturation                                                                                                                                                                 | 94 percent              | FDA-CBER-2022-1614-4434538 |

|    |            |                                                                                                                                                                                                                                                                                                                                                                                             |              |              |
|----|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------|
| 48 | 08/11/2020 | Platelet count                                                                                                                                                                                                                                                                                                                                                                              | 901 OTHER    | 400<br>140   |
| 49 | 08/17/2020 | Platelet count<br>thousand/uL                                                                                                                                                                                                                                                                                                                                                               | 618 OTHER    | 400<br>140   |
| 50 | 08/24/2020 | Platelet count<br>thousand/uL                                                                                                                                                                                                                                                                                                                                                               | 311 OTHER    | 400<br>140   |
| 51 | 08/01/2020 | Red blood cell count                                                                                                                                                                                                                                                                                                                                                                        | 3.52 10^12/L | 6.08<br>4.63 |
| 52 | 08/03/2020 | Red blood cell count                                                                                                                                                                                                                                                                                                                                                                        | 3.15 10^12/L | 6.08<br>4.63 |
| 53 | 08/05/2020 | Red blood cell count                                                                                                                                                                                                                                                                                                                                                                        | 3.27 10^12/L | 6.08<br>4.63 |
| 54 | 08/17/2020 | Red blood cell count<br>Million/uL                                                                                                                                                                                                                                                                                                                                                          | 3.79 OTHER   | 5.80<br>4.20 |
| 55 | 08/24/2020 | Red blood cell count<br>million/uL                                                                                                                                                                                                                                                                                                                                                          | 3.91 OTHER   | 5.80<br>4.20 |
| 56 | 07/29/2020 | Respiratory rate                                                                                                                                                                                                                                                                                                                                                                            | 19 /min      |              |
| 57 | 08/01/2020 | Respiratory rate                                                                                                                                                                                                                                                                                                                                                                            | 21 /min      |              |
| 58 | 08/05/2020 | Respiratory rate                                                                                                                                                                                                                                                                                                                                                                            | 17 /min      |              |
| 59 | 07/25/2020 | SARS-CoV-2 antibody test<br>Negative<br>Performed at the site                                                                                                                                                                                                                                                                                                                               | negative     |              |
| 60 | 07/29/2020 | SARS-CoV-2 antibody test<br>Negative                                                                                                                                                                                                                                                                                                                                                        | negative     |              |
| 61 | 08/01/2020 | SARS-CoV-2 antibody test<br>Negative<br>Performed in the ER                                                                                                                                                                                                                                                                                                                                 | negative     |              |
| 62 | 08/19/2020 | Ultrasound abdomen<br><br>Borderline hepatomegaly with increased echogenicity likely due to fatty replacement. No focal intrahepatic lesions seen. Gallbladder sludge layering dependently in the gallbladder. No definite calculi, wall thickening or pericholecystic fluid seen. Normal bile ducts. Mild aortic ectasia with maximum dimension of 34 millimeters in the proximal segment. |              |              |
| 63 | 08/01/2020 | Urine analysis<br>Negative                                                                                                                                                                                                                                                                                                                                                                  | negative     |              |
| 64 | 08/01/2020 | White blood cell count                                                                                                                                                                                                                                                                                                                                                                      | 13.4 10^9/L  | 10.0<br>4.0  |
| 65 | 08/03/2020 | White blood cell count                                                                                                                                                                                                                                                                                                                                                                      | 11.1 10^9/L  | 10.0<br>4.0  |
| 66 | 08/05/2020 | White blood cell count                                                                                                                                                                                                                                                                                                                                                                      | 12.6 10^9/L  | 10.0<br>4.0  |



## B7. OTHER RELEVANT HISTORY

| # | Start/Stop Date       | Condition Type / Condition                                    | Notes |
|---|-----------------------|---------------------------------------------------------------|-------|
| 1 | --/--/2000<br>Ongoing | Current Condition<br>Spinal osteoarthritis                    |       |
| 2 | --/--/2000<br>Ongoing | Current Condition<br>Spinal stenosis                          |       |
| 3 | --/--/2003<br>Ongoing | Current Condition<br>Attention deficit hyperactivity disorder |       |
| 4 | --/--/2008<br>Ongoing | Current Condition<br>Depression                               |       |
| 5 | --/--/2018<br>Ongoing | Current Condition<br>Erectile dysfunction                     |       |
| 6 | Ongoing               | Current Condition<br>Non-tobacco user                         |       |

## C4. DIAGNOSIS FOR USE (Continued)

#1: COVID-19 vaccination (COVID-19 immunisation)

## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

2) DULOXETINE HCL (DULOXETINE HCL) --/--/2015 to ongoing

3) MULTIVITAMIN /07504101/ (VITAMINS NOS) Tablet --/--/2015 to ongoing