

US3212013 (Prod: DM Clinical Research - ERN - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:46:15

All time stamps listed in this document are displayed in GMT

**US3212013**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:46:15**

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[Participant ID](#)

US3212013

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[mRNA-1273-P301 Completion Guidelines](#)

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:46:15

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 03 AUG 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | SCRN                                    |

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| Date of Birth (MMM yyyy)                  | (b) (6) 1975   |
| Age                                       | 45   |
| Age Units                                 | YEARS  |
| Age (Derived)                             | 45   |
| Sex                                       | Female <input checked="" type="radio"/><br>Male <input type="radio"/>  |
| Ethnicity                                 | Hispanic or Latino <input type="radio"/><br>Not Hispanic or Latino <input checked="" type="radio"/><br>Not Reported <input type="radio"/><br>Unknown <input type="radio"/> |
| Race (Check All That Apply)               |  |
| White                                     | True   |
| Black                                     | False  |
| Asian                                     | False  |
| American Indian or Alaska Native          | False  |
| Native Hawaiian or other Pacific Islander | False  |
| Other                                     | False  |
| If race is Other, specify _____           |  |
| Unknown                                   | False  |
| Not reported                              | False  |

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 3 AUG 2020                                   |
| Month and Year of Informed Consent (derived)    | AUG 2020                                     |
| Year of Informed Consent (derived)              | 2020   |
| Protocol Version                                | Amendment 1 <input checked="" type="radio"/> |
|   | Amendment 2 <input type="radio"/>            |
|   | Amendment 3 <input type="radio"/>            |
|   | Amendment 4 <input type="radio"/>            |
|   | Amendment 5 <input type="radio"/>            |
| Was participant enrolled in the study?          | Yes <input checked="" type="radio"/>         |
|   | No <input type="radio"/>                     |
| If No, indicate reason for screen fail          | Withdrew Consent <input type="radio"/>       |
|   | Inclusion/Exclusion <input type="radio"/>    |
|   | Cohort Full <input type="radio"/>            |
|   | Other <input type="radio"/>                  |
| If reason for screen fail is Other, specify     |  |
| Was this participant screened previously?       | Yes <input type="radio"/>                    |
|   | No <input checked="" type="radio"/>          |
| If Yes, previous participant number             |  |
| Enrollment Trigger                              | 1  |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:46:15

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 10:46:15**

[Were any significant conditions reported?](#)

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| Condition   | CESAREAN SECTION   |
| Start date (dd MMM yyyy)                          | 8 DEC 1993   |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | 8 DEC 1993   |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | DEC 1993   |
| Start Year (derived)                              | 1993   |
| Stop Month and Year (derived)                     | DEC 1993   |
| Stop Year (derived)                               | 1993   |



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Form: Medical History (2)

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| Condition   | CESAREAN SECTION   |
| Start date (dd MMM yyyy)                          | 31 AUG 1998  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | 31 AUG 1998  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | AUG 1998   |
| Start Year (derived)                              | 1998   |
| Stop Month and Year (derived)                     | AUG 1998   |
| Stop Year (derived)                               | 1998   |

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| Condition   | CESAREAN SECTION   |
| Start date (dd MMM yyyy)                          | 25 JUN 2002  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | 25 JUN 2002  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JUN 2002   |
| Start Year (derived)                              | 2002   |
| Stop Month and Year (derived)                     | JUN 2002   |
| Stop Year (derived)                               | 2002   |

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| Condition   | CHOLECYSTECTOMY  |
| Start date (dd MMM yyyy)                          | UN UNK 2016  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2016  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2016   |
| Start Year (derived)                              | 2016   |
| Stop Month and Year (derived)                     | JAN 2016   |
| Stop Year (derived)                               | 2016   |

US3212013

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Form: Medical History (5)

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| Condition   | CHOLELITHIASIS   |
| Start date (dd MMM yyyy)                          | UN UNK 2016  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2016  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2016   |
| Start Year (derived)                              | 2016   |
| Stop Month and Year (derived)                     | JAN 2016   |
| Stop Year (derived)                               | 2016   |

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Form: Medical History (6)

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| Condition   | BILATERAL TUBAL LIGATION   |
| Start date (dd MMM yyyy)                          | 25 JUN 2002  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | 25 JUN 2002  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JUN 2002   |
| Start Year (derived)                              | 2002   |
| Stop Month and Year (derived)                     | JUN 2002   |
| Stop Year (derived)                               | 2002   |

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| Condition   | SEASONAL ALLERGIES   |
| Start date (dd MMM yyyy)                          | UN UNK 2010  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2010   |
| Start Year (derived)                              | 2010   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Form: Medical History (8)

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| Condition   | IRON DEFICIENCY ANEMIA   |
| Start date (dd MMM yyyy)                          | UN UNK 2018  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2018   |
| Start Year (derived)                              | 2018   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Form: Medical History (9)

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| Condition   | GASTROESOPHAGEAL REFLUX DISEASE                                  |
| Start date (dd MMM yyyy)                          | UN UNK 2017  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2017   |
| Start Year (derived)                              | 2017   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |



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Form: Medical History (11)

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| Condition   | URINARY INCONTINENCE   |
| Start date (dd MMM yyyy)                          | UN UNK 2019  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2019   |
| Start Year (derived)                              | 2019   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

US3212013

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| Condition   | PERONEAL TEAR  |
| Start date (dd MMM yyyy)                          | UN FEB 2020  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN FEB 2020  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | FEB 2020   |
| Start Year (derived)                              | 2020   |
| Stop Month and Year (derived)                     | FEB 2020   |
| Stop Year (derived)                               | 2020   |

US3212013

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| Condition   | PERONEAL TENDON REPAIR   |
| Start date (dd MMM yyyy)                          | UN FEB 2020  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN FEB 2020  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | FEB 2020   |
| Start Year (derived)                              | 2020   |
| Stop Month and Year (derived)                     | FEB 2020   |
| Stop Year (derived)                               | 2020   |

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| Condition   | INTRAMURAL UTERINE<br>FIBROIDS                                   |
| Start date (dd MMM yyyy)                          | UN UNK 2012  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | 22 SEP 2020  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2012   |
| Start Year (derived)                              | 2012   |
| Stop Month and Year (derived)                     | SEP 2020   |
| Stop Year (derived)                               | 2020   |

US3212013

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| Condition   | OBESITY  |
| Start date (dd MMM yyyy)                                | 03 AUG 2020  |
| Start date completely unknown                           | False  |
| Condition ongoing at study entry                        | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ |  |
| Stop date completely unknown                            | False  |
| Start Month and Year (derived)                          | AUG 2020   |
| Start Year (derived)                                    | 2020   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

|   |                                      |
|---|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|   | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 3 AUG 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 14:06 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 3 AUG 2020 14:06                     |
| Height ( <i>xxx.x</i> )                   | 62 in                                |
| Weight ( <i>xxx.x</i> )                   | 200 lb                               |
| BMI ( <i>xxx.x</i> )                      | 36.65696 kg/m <sup>2</sup>           |
| BMI units                                 | KG/M2                                |
| Temperature ( <i>xxx.x</i> )              | ND - Not Done                        |
| Route of measurement                      | Oral <input type="radio"/>           |
|   | Axillary <input type="radio"/>       |
|   | Other <input type="radio"/>          |
| If Other, specify                         |                                      |
| Pulse ( <i>xxx</i> )                      | ND - Not Done                        |
| Pulse units                               | BPM                                  |
| Respiratory Rate ( <i>xxx</i> )           | ND - Not Done                        |
| Respiratory Rate units                    | BREATHS/MIN                          |
| Systolic Blood Pressure ( <i>xxx</i> )    | ND - Not Done                        |
| Systolic Blood Pressure units             | MMHG                                 |
| Diastolic Blood Pressure ( <i>xxx</i> )   | ND - Not Done                        |
| Diastolic Blood Pressure units            | MMHG                                 |
| Height (derived)                          |                                      |
| Weight (derived)                          |                                      |

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 AUG 2020

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:46:15

Date of assessment (*dd MMM yyyy*) 3 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

If No, what is the reason? Surgically sterile ☒  
Post-menopausal ☐  
Partner medically sterile ☐  
Not reached age of Menarche ☐  
Other ☐

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (*dd MMM yyyy*) 25 JUN 2002

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) \_\_\_\_\_

Date of last menstruation unknown False



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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

**Occupational Risk**

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☒ No ☐

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

**Warehouse shipping and fulfillment centers** and jobs (e.g., Amazon facilities) Yes ☐ No ☒

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

**Other** Yes ☐ No ☒

**Specify**

**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) True

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

|  |   |
|--|---|
| <b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)                                 | False   |
| <b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes) | False   |
| <b>Resides in a single family home</b> (i.e., detached housing)  | False   |
| <b>Other</b>   | True  |
| <b>Specify</b>   | PARTICIPANT LIVES WITH<br>CHILDREN IN THE HOUSEHOLD<br>LIKELY TO GO BACK TO<br>SCHOOL IN PERSON THIS YEAR |

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:46:15

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 03 AUG 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT1                                  |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:46:15

What was the date of randomization? (dd MMM yyyy) 03 AUG 2020

What was the participant's randomization number? 100752

In what Cohort was the participant enrolled?   
 >=18 and <65 years and not at risk ☒   
 >=18 and <65 years and at risk ☐   
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

|  |                                     |
|--|-------------------------------------|
| Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)     | Yes <input type="radio"/>           |
|  | No <input checked="" type="radio"/> |
| Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) | Yes <input type="radio"/>           |
|  | No <input checked="" type="radio"/> |
| Severe obesity (body mass index > or = 40kg/m2)  | Yes <input type="radio"/>           |
|  | No <input checked="" type="radio"/> |
| Diabetes (Type I, Type 2, or gestational)  | Yes <input type="radio"/>           |
|  | No <input checked="" type="radio"/> |
| Liver Disease  | Yes <input type="radio"/>           |
|  | No <input checked="" type="radio"/> |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 10:46:15**

|        |               |
|--------|---------------|
| Height | ND - Not Done |
| Weight | ND - Not Done |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

|                                     |  |
|-------------------------------------|--|
| Height                              | ND - Not Done  |
| Weight                              | ND - Not Done  |
| Timepoint                           | Pre-Dose <input checked="" type="radio"/><br>Post-Dose <input type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 3 AUG 2020   |
| Time of assessment (00:00-23:59)    | 14:06 (24 HR)  |
| Vital Signs Date and Time (derived) | 3 AUG 2020 14:06   |
| Temperature (xxx.x)                 | 97.4 F   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 68 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 12 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 142 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 92 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

|                                     |  |
|-------------------------------------|--|
| Height                              | ND - Not Done  |
| Weight                              | ND - Not Done  |
| Timepoint                           | Pre-Dose <input type="radio"/><br>Post-Dose <input checked="" type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 3 AUG 2020   |
| Time of assessment (00:00-23:59)    | 16:52 (24 HR)  |
| Vital Signs Date and Time (derived) | 3 AUG 2020 16:52   |
| Temperature (xxx.x)                 | 97.1 F   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 76 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 132 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 84 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3212013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:15

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*



US3212013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:46:15

|  |  |
|--|--|
| Was study treatment given?   | Yes <input checked="" type="radio"/>                               |
|  | No <input type="radio"/>   |
| If No, reason not given  | Participant declined due to Adverse Event <input type="radio"/>    |
|  | Physician withheld dose due to Adverse Event <input type="radio"/> |
|  | Death <input type="radio"/>  |
|  | Lost To Follow-Up <input type="radio"/>                            |
|  | Physician Decision <input type="radio"/>                           |
|  | Pregnancy <input type="radio"/>                                    |
|  | Protocol Deviation <input type="radio"/>                           |
|  | Study Terminated by Sponsor <input type="radio"/>                  |
|  | Withdrawal of Consent by Participant <input type="radio"/>         |
|  | Confirmed COVID-19 <input type="radio"/>                           |
|  | Other <input type="radio"/>  |
| If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify |  |
| What was the study treatment?  | MRNA-1273 OR PLACEBO   |
| What was the treatment date? (dd MMM yyyy)   | 03 AUG 2020  |
| What was the treatment time? (00:00-23:59)   | 16:19 (24 HR)  |
| Treatment Date and Time (derived)  | 03 AUG 2020 16:19  |
| Which arm was used to give treatment?  | Left Arm <input checked="" type="radio"/>                          |
|  | Right Arm <input type="radio"/>                                    |
| What was the frequency of the study treatment dosing?  | ONCE   |
| What was the route of administration for the study treatment?  | INTRAMUSCULAR  |

US3212013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:15

|  |                                      |
|--|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 3 AUG 2020                           |
| Collection time ( <i>00:00-23:59</i> ) | 15:37 (24 HR)                        |
| Collection date and time (derived)     | 3 AUG 2020 15:37                     |

US3212013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:46:15

|  |                           |  |                                    |
|--|---------------------------|--|------------------------------------|
| Collection date ( <i>dd MMM yyyy</i> ) |                           |  | 3 AUG 2020                         |
| Lab Test                               | Was the sample collected? | Collection time ( <i>00:00 - 23:59</i> ) | Collection date and time (derived) |
| Nasopharyngeal Swab 1                  | Yes                       | 15:30                                    | 3 AUG 2020 15:30                   |
| Nasopharyngeal Swab 2                  | No                        |  |                                    |

US3212013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:46:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

03 AUG 2020 16:55

PC Open Date & Time

03 AUG 2020 16:39

PC Close Date & Time

03 AUG 2020 19:09

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °F

Was any **MEDICATION TAKEN today for pain or fever?** Yes ☐ No ☒

Please confirm reason for pain or fever medication (may select more than one):

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 03 AUG 2020 21:40 |
| PC Open Date & Time  | 03 AUG 2020 20:04 |
| PC Close Date & Time | 04 AUG 2020 11:59 |

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:46:15

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**TIMEPOINT**

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

Was any **MEDICATION TAKEN today for pain or fever?**

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

04 AUG 2020 18:06

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:46:15

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**TIMEPOINT**

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.5 °F

---

Was any **MEDICATION TAKEN today for pain or fever?**

Yes ☐

No ☒

---

Please confirm reason for pain or fever medication (may select more than one):

---

PC Time Stamp

05 AUG 2020 17:39

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PC Open Date & Time

05 AUG 2020 12:00

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PC Close Date & Time

06 AUG 2020 11:59

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US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:46:15

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**TIMEPOINT**

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

Was any **MEDICATION TAKEN today for pain or fever?**

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

06 AUG 2020 14:54

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:46:15

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**TIMEPOINT**

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

99.2 °F

---

Was any **MEDICATION TAKEN today for pain or fever?**

Yes ☐

No ☒

---

Please confirm reason for pain or fever medication (may select more than one):

---

PC Time Stamp

07 AUG 2020 18:08

---

PC Open Date & Time

07 AUG 2020 12:00

---

PC Close Date & Time

08 AUG 2020 11:59

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US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:46:15

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**TIMEPOINT**

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

08 AUG 2020 18:05

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

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If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

09 AUG 2020 12:48

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 16:56

PC Open Date & Time

03 AUG 2020 16:39

PC Close Date & Time

03 AUG 2020 19:09

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 21:41

PC Open Date & Time

03 AUG 2020 20:04

PC Close Date & Time

04 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☒

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE**  
(in mm)

1

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 16:27

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 17:39

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59



US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 14:49

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 18:09

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 18:06

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 12:49

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:46:15

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 03 AUG 2020 16:56 |
| PC Open Date & Time  | 03 AUG 2020 16:39 |
| PC Close Date & Time | 03 AUG 2020 19:09 |

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:46:15

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 03 AUG 2020 21:41 |
| PC Open Date & Time  | 03 AUG 2020 20:04 |
| PC Close Date & Time | 04 AUG 2020 11:59 |



US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or  
1-2 episodes/24 hours ☒

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:46:15

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 04 AUG 2020 16:28 |
| PC Open Date & Time          | 04 AUG 2020 12:00 |
| PC Close Date & Time         | 05 AUG 2020 11:59 |

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
other) for any illness or symptoms?

No ☒

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:46:15

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 05 AUG 2020 17:39 |
| PC Open Date & Time          | 05 AUG 2020 12:00 |
| PC Close Date & Time         | 06 AUG 2020 11:59 |

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:46:15

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 06 AUG 2020 14:50 |
| PC Open Date & Time          | 06 AUG 2020 12:00 |
| PC Close Date & Time         | 07 AUG 2020 11:59 |

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:46:15

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 07 AUG 2020 18:09 |
| PC Open Date & Time          | 07 AUG 2020 12:00 |
| PC Close Date & Time         | 08 AUG 2020 11:59 |



US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:46:15

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 08 AUG 2020 18:06 |
| PC Open Date & Time          | 08 AUG 2020 12:00 |
| PC Close Date & Time         | 09 AUG 2020 11:59 |

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:46:15

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 09 AUG 2020 12:49 |
| PC Open Date & Time          | 09 AUG 2020 12:00 |
| PC Close Date & Time         | 10 AUG 2020 11:59 |

US3212013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

10 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3212013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3212013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3212013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3212013

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:15

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 7 OCT 2020                              |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT2                                  |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

|                                     |   |
|-------------------------------------|---|
| Timepoint                           | Pre-Dose <input checked="" type="radio"/> |
|                                     | Post-Dose <input type="radio"/>           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of assessment (dd MMM yyyy)    | 7 OCT 2020                                |
| Time of assessment (00:00-23:59)    | 14:58 (24 HR)                             |
| Vital Signs Date and Time (derived) | 7 OCT 2020 14:58                          |
| Temperature (xxx.x)                 | 97.5 F                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |   |
| Pulse (xxx)                         | 88 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 14 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 124 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 88 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

|                                     |  |
|-------------------------------------|--|
| Timepoint                           | Pre-Dose <input type="radio"/>             |
|                                     | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>       |
|                                     | No <input type="radio"/>                   |
| Date of assessment (dd MMM yyyy)    | 07 OCT 2020                                |
| Time of assessment (00:00-23:59)    | 16:28 (24 HR)                              |
| Vital Signs Date and Time (derived) | 07 OCT 2020 16:28                          |
| Temperature (xxx.x)                 | 98.2 F                                     |
| Route of measurement                | Oral <input checked="" type="radio"/>      |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input type="radio"/>                |
| If Other, specify                   |  |
| Pulse (xxx)                         | 75 beats/min                               |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min                             |
| Respiratory Rate units              | BREATHS/MIN                                |
| Systolic Blood Pressure (xxx)       | 132 mmHg                                   |
| Systolic Blood Pressure units       | MMHG                                       |
| Diastolic Blood Pressure (xxx)      | 88 mmHg                                    |
| Diastolic Blood Pressure units      | MMHG                                       |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 OCT 2020

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3212013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:46:15

|  |  |
|--|--|
| Was study treatment given?   | Yes <input checked="" type="radio"/>                               |
|  | No <input type="radio"/>   |
| If No, reason not given  | Participant declined due to Adverse Event <input type="radio"/>    |
|  | Physician withheld dose due to Adverse Event <input type="radio"/> |
|  | Death <input type="radio"/>  |
|  | Lost To Follow-Up <input type="radio"/>                            |
|  | Physician Decision <input type="radio"/>                           |
|  | Pregnancy <input type="radio"/>                                    |
|  | Protocol Deviation <input type="radio"/>                           |
|  | Study Terminated by Sponsor <input type="radio"/>                  |
|  | Withdrawal of Consent by Participant <input type="radio"/>         |
|  | Confirmed COVID-19 <input type="radio"/>                           |
|  | Other <input type="radio"/>  |
| If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify |  |
| What was the study treatment?  | MRNA-1273 OR PLACEBO   |
| What was the treatment date? (dd MMM yyyy)   | 7 OCT 2020   |
| What was the treatment time? (00:00-23:59)   | 15:43 (24 HR)  |
| Treatment Date and Time (derived)  | 7 OCT 2020 15:43   |
| Which arm was used to give treatment?  | Left Arm <input checked="" type="radio"/>                          |
|  | Right Arm <input type="radio"/>                                    |
| What was the frequency of the study treatment dosing?  | ONCE   |
| What was the route of administration for the study treatment?  | INTRAMUSCULAR  |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:15

|  |                                      |
|--|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 07 OCT 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 15:25 (24 HR)                        |
| Collection date and time (derived)     | 07 OCT 2020 15:25                    |



US3212013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:46:15

| Collection date (dd MMM yyyy) |                           |                                 | 7 OCT 2020                         |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 15:20                           | 7 OCT 2020 15:20                   |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

07 OCT 2020 16:20

PC Open Date & Time

07 OCT 2020 16:03

PC Close Date & Time

07 OCT 2020 18:33

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 99.1 °F

Was any **MEDICATION TAKEN today for pain or fever?** Yes ☐ No ☒

Please confirm reason for pain or fever medication (may select more than one):

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 07 OCT 2020 22:20 |
| PC Open Date & Time  | 07 OCT 2020 19:28 |
| PC Close Date & Time | 08 OCT 2020 11:59 |

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:46:15

---

**TIMEPOINT**

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

08 OCT 2020 13:56

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:46:15

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**TIMEPOINT**

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.9 °F

---

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

---

Please confirm reason for pain or fever medication (may select more than one):

---

PC Time Stamp

09 OCT 2020 22:21

---

PC Open Date & Time

09 OCT 2020 12:00

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PC Close Date & Time

10 OCT 2020 11:59

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US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:46:15

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**TIMEPOINT**

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

10 OCT 2020 18:20

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:46:15

---

**TIMEPOINT**

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.9 °F

---

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

---

Please confirm reason for pain or fever medication (may select more than one):

---

PC Time Stamp

12 OCT 2020 00:00

---

PC Open Date & Time

11 OCT 2020 12:00

---

PC Close Date & Time

12 OCT 2020 11:59

---



US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:46:15

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**TIMEPOINT**

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

99.0 °F

---

Was any **MEDICATION TAKEN today for pain or fever?**

Yes ☐

No ☒

---

Please confirm reason for pain or fever medication (may select more than one):

---

PC Time Stamp

13 OCT 2020 00:47

---

PC Open Date & Time

12 OCT 2020 12:00

---

PC Close Date & Time

13 OCT 2020 11:59

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US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

13 OCT 2020 22:28

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 16:21

PC Open Date & Time

07 OCT 2020 16:03

PC Close Date & Time

07 OCT 2020 18:33

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 22:21

PC Open Date & Time

07 OCT 2020 19:28

PC Close Date & Time

08 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 13:57

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 22:21

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 OCT 2020 18:19

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 OCT 2020 00:00

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59



US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 00:48

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 22:28

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:46:15

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 07 OCT 2020 16:21 |
| PC Open Date & Time  | 07 OCT 2020 16:03 |
| PC Close Date & Time | 07 OCT 2020 18:33 |

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:46:15

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 07 OCT 2020 22:22 |
| PC Open Date & Time  | 07 OCT 2020 19:28 |
| PC Close Date & Time | 08 OCT 2020 11:59 |

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
other) for any illness or symptoms?

No ☒

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:46:15

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 08 OCT 2020 13:57 |
| PC Open Date & Time          | 08 OCT 2020 12:00 |
| PC Close Date & Time         | 09 OCT 2020 11:59 |



US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:46:15

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 09 OCT 2020 22:21 |
| PC Open Date & Time          | 09 OCT 2020 12:00 |
| PC Close Date & Time         | 10 OCT 2020 11:59 |

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:46:15

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 10 OCT 2020 18:19 |
| PC Open Date & Time          | 10 OCT 2020 12:00 |
| PC Close Date & Time         | 11 OCT 2020 11:59 |

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:46:15

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 12 OCT 2020 00:00 |
| PC Open Date & Time          | 11 OCT 2020 12:00 |
| PC Close Date & Time         | 12 OCT 2020 11:59 |

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:46:15

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 13 OCT 2020 00:48 |
| PC Open Date & Time          | 12 OCT 2020 12:00 |
| PC Close Date & Time         | 13 OCT 2020 11:59 |



US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
other) for any illness or symptoms?

No ☒

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:46:15

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 13 OCT 2020 22:28 |
| PC Open Date & Time          | 13 OCT 2020 12:00 |
| PC Close Date & Time         | 14 OCT 2020 11:59 |

US3212013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3212013

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3212013

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3212013

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3212013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:15

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 4 NOV 2020                              |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT3                                  |

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

|   |                                       |
|---|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|   | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 4 NOV 2020                            |
| Time of assessment ( <i>00:00-23:59</i> ) | 14:24 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 4 NOV 2020 14:24                      |
| Temperature ( <i>xxx.x</i> )              | 97.2 F                                |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|   | Axillary <input type="radio"/>        |
|   | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | 80 beats/min                          |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 18 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 102 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 79 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

US3212013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 NOV 2020

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3212013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:15

|  |                                      |
|--|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 4 NOV 2020                           |
| Collection time ( <i>00:00-23:59</i> ) | 15:21 (24 HR)                        |
| Collection date and time (derived)     | 4 NOV 2020 15:21                     |

US3212013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 64   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Date and time of submission   | 07 OCT 2020 14:31:59   |
| Patient Cloud Open Date & Time  | 03 OCT 2020 00:01  |
| Patient Cloud Close Date & Time   | 07 OCT 2020 23:59  |

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 71

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

10 OCT 2020 00:20:48

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 78

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

21 OCT 2020 02:40:54

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59



US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 92

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

31 OCT 2020 17:15:30

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 99

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

07 NOV 2020 00:48:32

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 106

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

14 NOV 2020 00:32:09

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 61  |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2020 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2020 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 68  |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 OCT 2020 00:01

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[Patient Cloud Close Date & Time](#)

11 OCT 2020 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 75  |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2020 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 82   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 21 OCT 2020 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 25 OCT 2020 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 89  |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 28 OCT 2020 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 01 NOV 2020 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 96   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

08 NOV 2020 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 11 NOV 2020 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 NOV 2020 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 110  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 18 NOV 2020 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 22 NOV 2020 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 117  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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25 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2020 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 124  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 131   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 09 DEC 2020 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 13 DEC 2020 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 138

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 145  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 23 DEC 2020 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 27 DEC 2020 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 152  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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30 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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03 JAN 2021 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 159  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 166  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 173

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 180  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 187  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 03 FEB 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 07 FEB 2021 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 194  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 201  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 208

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 FEB 2021 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 215  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAR 2021 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 222  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 10 MAR 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 14 MAR 2021 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 229

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 17 MAR 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 21 MAR 2021 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 236  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAR 2021 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 243

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 250  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 257

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 264  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 271   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 278  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 285

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2021 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 292  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 299

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 306  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 313

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 320  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 327

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 334  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 341  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 JUL 2021 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 348  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 14 JUL 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 18 JUL 2021 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 355

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 362

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 369

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 376

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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11 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 AUG 2021 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 383

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 390

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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25 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 AUG 2021 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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01 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 SEP 2021 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 404  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 411  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 15 SEP 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 SEP 2021 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 418

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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22 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 SEP 2021 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 425

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 432

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 439

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 446  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 453

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 27 OCT 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 31 OCT 2021 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 460   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 467  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 10 NOV 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 14 NOV 2021 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 474  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 17 NOV 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 21 NOV 2021 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 481  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 488  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 495  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 502

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 15 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 DEC 2021 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 22 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 26 DEC 2021 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 516  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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29 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 530

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 12 JAN 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 16 JAN 2022 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 544

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 FEB 2022 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 16 FEB 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 20 FEB 2022 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 23 FEB 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 27 FEB 2022 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAR 2022 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 16 MAR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 20 MAR 2022 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 600  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 607  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 30 MAR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 03 APR 2022 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 614

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 06 APR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 10 APR 2022 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 621   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 628

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 20 APR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 24 APR 2022 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 635  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 642

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 649

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 656

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 670  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 684  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 15 JUN 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 JUN 2022 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 691  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 22 JUN 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 26 JUN 2022 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 705  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 06 JUL 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 10 JUL 2022 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 712  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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13 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 JUL 2022 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 719

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3212013**

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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

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24 JUL 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 726  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

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07 AUG 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 740   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 747

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 AUG 2022 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

| TIMEPOINT   | DAY 761   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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31 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 SEP 2022 23:59

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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

**TIMEPOINT**

DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 07 SEP 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 11 SEP 2022 23:59 |

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:46:15

TIMEPOINT

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

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**US3212013**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



**US3212013**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:46:15**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3212013**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:46:15**

|  |   |
|--|---|
| Date of Contact                                  |   |
| Time of Contact                                  |   |
| Date and Time of Contact (derived)               |   |
| Type of Contact                                  | Clinic Visit - Scheduled <input type="checkbox"/>     |
|  | Clinical Visit - Unscheduled <input type="checkbox"/> |
|  | Safety Call <input type="checkbox"/>                  |
|  | Convalescent Tele-visit <input type="checkbox"/>      |
| Has the subject reported symptoms of SARS-COV-2? | Yes <input type="checkbox"/>                          |
|  | No <input type="checkbox"/>                           |

**US3212013**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 26 Nov 2020 10:46:15**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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**US3212013**

**Folder: Unscheduled (4)**

**Form: Unscheduled Visit Assessment**

**Generated On: 26 Nov 2020 10:46:15**

|   |  |
|---|--|
| Visit Date  |  |
| <b>Please check all assessments that apply for this visit</b> |  |
| Physical Exam   |  |
| Vital Signs   |  |
| Immunogenicity Assessment                                     |  |
| Pregnancy Test  |  |

US3212013

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:46:15

Visit Date

Please check all assessments that apply for this visit

|                           |       |
|---------------------------|-------|
| Physical Exam             | False |
| Vital Signs               | False |
| Immunogenicity Assessment | False |
| Pregnancy Test            | False |

US3212013

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

|   |                                   |
|---|-----------------------------------|
| Were vital signs assessed?                | Yes <input type="checkbox"/>      |
|   | No <input type="checkbox"/>       |
| Date of assessment ( <i>dd MMM yyyy</i> ) |                                   |
| Time of assessment ( <i>00:00-23:59</i> ) |                                   |
| Vital Signs Date and Time (derived)       |                                   |
| Temperature ( <i>xxx.x</i> )              |                                   |
| Route of measurement                      | Oral <input type="checkbox"/>     |
|   | Axillary <input type="checkbox"/> |
|   | Other <input type="checkbox"/>    |
| If Other, specify                         |                                   |
| Pulse ( <i>xxx</i> )                      |                                   |
| Pulse units                               |                                   |
| Respiratory Rate ( <i>xxx</i> )           |                                   |
| Respiratory Rate units                    |                                   |
| Systolic Blood Pressure ( <i>xxx</i> )    |                                   |
| Systolic Blood Pressure units             |                                   |
| Diastolic Blood Pressure ( <i>xxx</i> )   |                                   |
| Diastolic Blood Pressure units            |                                   |
| Height (derived)                          |                                   |
| Weight (derived)                          |                                   |

US3212013

Folder: Unscheduled 15 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:46:15

Visit Date

Please check all assessments that apply for this visit

|                           |       |
|---------------------------|-------|
| Physical Exam             | False |
| Vital Signs               | False |
| Immunogenicity Assessment | False |
| Pregnancy Test            | False |

US3212013

Folder: **Unscheduled 29 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **26 Nov 2020 10:46:15**

|            |             |
|------------|-------------|
| Visit Date | 29 SEP 2020 |
|------------|-------------|

**Please check all assessments that apply for this visit**

|               |      |
|---------------|------|
| Physical Exam | True |
|---------------|------|

|             |      |
|-------------|------|
| Vital Signs | True |
|-------------|------|

|                           |       |
|---------------------------|-------|
| Immunogenicity Assessment | False |
|---------------------------|-------|

|                |       |
|----------------|-------|
| Pregnancy Test | False |
|----------------|-------|



US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

|   |                                       |
|---|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|   | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 29 SEP 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 14:47 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 29 SEP 2020 14:47                     |
| Temperature ( <i>xxx.x</i> )              | 97.3 F                                |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|   | Axillary <input type="radio"/>        |
|   | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | 83 beats/min                          |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 15 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 126 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 84 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3212013

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:46:15

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:15

|  |  |
|--|--|
| AEID   | USA-US115-2020-MRNA-1273-P30<br>1000003  |
| Adverse event  | ABNORMAL UTERINE<br>BLEEDING   |
| Was this a medically-attended AE?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Start date (dd MMM yyyy)                                       | 27 AUG 2020  |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         | 28 AUG 2020  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input checked="" type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| AE is serious due To (check all that apply)                    |  |
| Death  | False  |
| Life threatening   | False  |
| Requires inpatient or prolongation of existing Hospitalization | True   |
| Hospital Admission Date (dd MMM yyyy)                          | 27 AUG 2020  |
| Hospital Discharge Date (dd MMM yyyy)                          | 28 AUG 2020  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/><br>Unknown <input type="radio"/>  |
| Number of Days in ICU  |  |

v6.020 DTW (1102)

355 of 2347

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:15

|  |   |
|--|---|
| Persistent or significant disability or incapacity                           | False   |
| Congenital anomaly or birth defect   | False   |
| Other medically important event  | False   |
| Relationship to investigational product                                      | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Relationship to Study Procedure  | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Action taken with investigational product                                    | None <input type="radio"/><br>Dose Delayed <input checked="" type="radio"/><br>Investigational Product <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Other action taken (check all that apply)                                    |   |
| None   | False   |
| Concomitant Medication   | True  |
| Concomitant Procedure  | True  |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |   |
| Narrative  |   |

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:15

---

PATIENT HAS A HISTORY OF  
UTERINE FIBROIDS. ON  
27AUG2020 SHE PRESENTED TO  
MEMORIAL HERMANN  
HOSPITAL WITH UTERINE  
HEMORRHAGE. SHE WAS  
ADMITTED TO HOSPITAL AND  
RECEIVED 3 PINTS OF  
TRANSFUSED BLOOD. SHE WAS  
PRESCRIBED HORMONAL  
CONTRACEPTION AS WELL.  
SHE WAS DISCHARGED ON  
28AUG2020. RECORDS WILL BE  
REQUESTED BY SITE. IP IS  
BEING DELAYED DUE TO  
PARTICIPANT'S RECEIVING  
BLOOD TRANSFUSIONS.

---

|  |   |
|--|---|
| Serious Adverse Event Derived (CSA Programming Field Only) | 1 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only)       | 0 |

---

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:46:15

|  |  |
|--|--|
| AEID   |  |
| Adverse event  | URINARY TRACT INFECTION  |
| Was this a medically-attended AE?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Start date (dd MMM yyyy)                                       | 12 OCT 2020  |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         | 19 OCT 2020  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input checked="" type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| AE is serious due To (check all that apply)                    |  |
| Death  | False  |
| Life threatening   | False  |
| Requires inpatient or prolongation of existing Hospitalization | False  |
| Hospital Admission Date (dd MMM yyyy)                          |  |
| Hospital Discharge Date (dd MMM yyyy)                          |  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>   |
| Number of Days in ICU  |  |
| Persistent or significant disability or incapacity             | False  |

v6.020 DTW (1102)

358 of 2347

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:46:15

|  |   |
|--|---|
| Congenital anomaly or birth defect   | False   |
| Other medically important event  | False   |
| Relationship to investigational product                                      | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Relationship to Study Procedure  | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Action taken with investigational product                                    | None <input checked="" type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product Withdrawn <input type="radio"/><br>Not Applicable <input type="radio"/>  |
| Other action taken (check all that apply)                                    |   |
| None   | False   |
| Concomitant Medication   | True  |
| Concomitant Procedure  | False   |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |   |
| Narrative  |   |
| Serious Adverse Event Derived (CSA Programming Field Only)                   | 0   |
| Medically Attended AE Derived (CSA Programming Field Only)                   | 1   |
| Admitted to ICU Derived (CSA Programming Field Only)                         |   |



US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:46:15

|  |  |
|--|--|
| AEID   | USA-US115-2020-MRNA-1273-P30<br>1000003  |
| Adverse event  | WORSENING OF ABNORMAL<br>UTERINE BLEEDING  |
| Was this a medically-attended AE?                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Start date (dd MMM yyyy)                                       | 22 SEP 2020  |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         | 22 SEP 2020  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input checked="" type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| AE is serious due To (check all that apply)                    |  |
| Death  | False  |
| Life threatening   | False  |
| Requires inpatient or prolongation of existing Hospitalization | True   |
| Hospital Admission Date (dd MMM yyyy)                          | 22 SEP 2020  |
| Hospital Discharge Date (dd MMM yyyy)                          | 23 SEP 2020  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/><br>Unknown <input type="radio"/>  |
| Number of Days in ICU  |  |

v6.020 DTW (1102)

360 of 2347

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:46:15

|  |   |
|--|---|
| Persistent or significant disability or incapacity                           | False   |
| Congenital anomaly or birth defect   | False   |
| Other medically important event  | False   |
| Relationship to investigational product                                      | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Relationship to Study Procedure  | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Action taken with investigational product                                    | None <input type="radio"/><br>Dose Delayed <input checked="" type="radio"/><br>Investigational Product <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Other action taken (check all that apply)                                    |   |
| None   | False   |
| Concomitant Medication   | False   |
| Concomitant Procedure  | True  |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |   |
| Narrative  | SUBJECT UNDERWENT<br>HYSTERECTOMY FOR UTERINE<br>BLEEDING/FIBROIDS.   |
| Serious Adverse Event Derived (CSA Programming Field Only)                   | 1   |
| Medically Attended AE Derived (CSA Programming Field Only)                   | 0   |
| Admitted to ICU Derived (CSA Programming Field Only)                         | 0   |

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:46:15

AEID

Adverse event

RIGHT FOOT PAIN (PLANTAR  
FASCIITIS)

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

22 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

v6.020 DTW (1102)

362 of 2347

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:46:15

|  |   |
|--|---|
| Persistent or significant disability or incapacity                           | False   |
| Congenital anomaly or birth defect   | False   |
| Other medically important event  | False   |
| Relationship to investigational product                                      | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Relationship to Study Procedure  | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Action taken with investigational product                                    | None <input checked="" type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Other action taken (check all that apply)                                    |   |
| None   | False   |
| Concomitant Medication   | True  |
| Concomitant Procedure  | False   |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input checked="" type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |   |
| Narrative  |   |
| Serious Adverse Event Derived (CSA Programming Field Only)                   | 0   |
| Medically Attended AE Derived (CSA Programming Field Only)                   | 1   |
| Admitted to ICU Derived (CSA Programming Field Only)                         |   |

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:46:15

|  |  |
|--|--|
| AEID   |  |
| Adverse event  | VAGINAL CANDIDIASIS  |
| Was this a medically-attended AE?                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Start date (dd MMM yyyy)                                       | 20 OCT 2020  |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         |  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input checked="" type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| AE is serious due To (check all that apply)                    |  |
| Death  | False  |
| Life threatening   | False  |
| Requires inpatient or prolongation of existing Hospitalization | False  |
| Hospital Admission Date (dd MMM yyyy)                          |  |
| Hospital Discharge Date (dd MMM yyyy)                          |  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>   |
| Number of Days in ICU  |  |
| Persistent or significant disability or incapacity             | False  |

v6.020 DTW (1102)

364 of 2347

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:46:15

|  |   |
|--|---|
| Congenital anomaly or birth defect   | False   |
| Other medically important event  | False   |
| Relationship to investigational product                                      | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Relationship to Study Procedure  | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Action taken with investigational product                                    | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>  |
| Other action taken (check all that apply)                                    |   |
| None   | False   |
| Concomitant Medication   | True  |
| Concomitant Procedure  | False   |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input checked="" type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |   |
| Narrative  |   |
| Serious Adverse Event Derived (CSA Programming Field Only)                   | 0   |
| Medically Attended AE Derived (CSA Programming Field Only)                   | 0   |
| Admitted to ICU Derived (CSA Programming Field Only)                         |   |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:46:15

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

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If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:15

|                                |  |
|--------------------------------|--|
| Name of Medication             | OXYBUTYNIN   |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                     | URINARY INCONTINENCE   |
| Dose per administration        | 5  |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify |  |
| Frequency                      | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |  |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>  |



US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:15

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN                       | UNK 2019                         |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:15

|                                      |   |
|--------------------------------------|---|
| Name of Medication                   | ESMOPRAZOLE ( NEXIUM )  |
| Prophylaxis                          | Yes <input type="checkbox"/><br>No <input checked="" type="checkbox"/>  |
| Indication                           | GASTROESOPHAGEAL REFLUX<br>DISEASE  |
| Dose per administration              | 20  |
| Dose unit                            | mg <input checked="" type="checkbox"/><br>ug <input type="checkbox"/><br>mL <input type="checkbox"/><br>g <input type="checkbox"/><br>IU <input type="checkbox"/><br>tablet <input type="checkbox"/><br>capsule <input type="checkbox"/><br>puff <input type="checkbox"/><br>Other <input type="checkbox"/>   |
| If dose unit is Other, specify _____ |   |
| Frequency                            | once daily <input checked="" type="checkbox"/><br>twice daily <input type="checkbox"/><br>three times daily <input type="checkbox"/><br>four times daily <input type="checkbox"/><br>every other day <input type="checkbox"/><br>every week <input type="checkbox"/><br>every month <input type="checkbox"/><br>as needed <input type="checkbox"/><br>once <input type="checkbox"/><br>unknown <input type="checkbox"/><br>other <input type="checkbox"/> |
| If frequency is Other, specify _____ |   |
| Route of administration              | Oral <input checked="" type="checkbox"/><br>Topical <input type="checkbox"/><br>Subcutaneous <input type="checkbox"/><br>Transdermal <input type="checkbox"/><br>Intraocular <input type="checkbox"/>   |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:15

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="radio"/>            |
|  | Respiratory (Inhalation) | <input type="radio"/>            |
|  | Intralesional            | <input type="radio"/>            |
|  | Intraperitoneal          | <input type="radio"/>            |
|  | Nasal                    | <input type="radio"/>            |
|  | Vaginal                  | <input type="radio"/>            |
|  | Rectal                   | <input type="radio"/>            |
|  | Intravenous              | <input type="radio"/>            |
|  | Intravenous Bolus        | <input type="radio"/>            |
|  | Intravenous Drip         | <input type="radio"/>            |
|  | Other                    | <input type="radio"/>            |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN                       | UNK 2019                         |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:15

|                                |   |
|--------------------------------|---|
| Name of Medication             | FERROUS SULPHATE  |
| Prophylaxis                    | Yes <input type="checkbox"/><br>No <input checked="" type="checkbox"/>  |
| Indication                     | IRON DEFICIENCY   |
| Dose per administration        | 65  |
| Dose unit                      | mg <input checked="" type="checkbox"/><br>ug <input type="checkbox"/><br>mL <input type="checkbox"/><br>g <input type="checkbox"/><br>IU <input type="checkbox"/><br>tablet <input type="checkbox"/><br>capsule <input type="checkbox"/><br>puff <input type="checkbox"/><br>Other <input type="checkbox"/>   |
| If dose unit is Other, specify |   |
| Frequency                      | once daily <input checked="" type="checkbox"/><br>twice daily <input type="checkbox"/><br>three times daily <input type="checkbox"/><br>four times daily <input type="checkbox"/><br>every other day <input type="checkbox"/><br>every week <input type="checkbox"/><br>every month <input type="checkbox"/><br>as needed <input type="checkbox"/><br>once <input type="checkbox"/><br>unknown <input type="checkbox"/><br>other <input type="checkbox"/> |
| If frequency is Other, specify |   |
| Route of administration        | Oral <input checked="" type="checkbox"/><br>Topical <input type="checkbox"/><br>Subcutaneous <input type="checkbox"/><br>Transdermal <input type="checkbox"/><br>Intraocular <input type="checkbox"/><br>Intramuscular <input type="checkbox"/>   |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:15

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| <hr/>  |                          |                                     |
| If route of administration is Other, specify <hr/> |                          |                                     |
| Start date (dd MMM yyyy)                           | UN                       | UNK 2018                            |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| <hr/>  |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)             | UN                       | AUG 2020                            |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| <hr/>  |                          |                                     |
| Separate Dosage Number (derived)                   | 1                        |                                     |
| Interval Dosage Unit Number (derived)              | 1                        |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:15

|                                |  |
|--------------------------------|--|
| Name of Medication             | CETIRIZINE ( ZYRTEC )  |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                     | SEASONAL ALLERGIES   |
| Dose per administration        | 10   |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify |  |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |  |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>  |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:15

|   |                          |                                  |
|---|--------------------------|----------------------------------|
|   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|   | Intralesional            | <input type="checkbox"/>         |
|   | Intraperitoneal          | <input type="checkbox"/>         |
|   | Nasal                    | <input type="checkbox"/>         |
|   | Vaginal                  | <input type="checkbox"/>         |
|   | Rectal                   | <input type="checkbox"/>         |
|   | Intravenous              | <input type="checkbox"/>         |
|   | Intravenous Bolus        | <input type="checkbox"/>         |
|   | Intravenous Drip         | <input type="checkbox"/>         |
|   | Other                    | <input type="checkbox"/>         |
| <hr/>   |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>   |                          |                                  |
| Start date (dd MMM yyyy)  | UN                       | UNK 2010                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?  | Yes                      | <input checked="" type="radio"/> |
|   | No                       | <input type="radio"/>            |
| <hr/>   |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>   |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|   | No                       | <input checked="" type="radio"/> |
| <hr/>   |                          |                                  |
| Separate Dosage Number (derived)                                  | <input type="text"/>     |                                  |
| Interval Dosage Unit Number (derived)                             | <input type="text"/>     |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|   | 803                      | <input type="radio"/>            |
|   | 804                      | <input type="radio"/>            |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:15

|                                      |  |
|--------------------------------------|--|
| Name of Medication                   | PROVERA  |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                           | UTERINE BLEEDING   |
| Dose per administration              | 10   |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify _____ |  |
| Frequency                            | once daily <input type="radio"/><br>twice daily <input checked="" type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |  |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>  |



US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:15

|   |                                      |                                     |
|---|--------------------------------------|-------------------------------------|
|   | Respiratory (Inhalation)             | <input type="checkbox"/>            |
|   | Intralesional                        | <input type="checkbox"/>            |
|   | Intraperitoneal                      | <input type="checkbox"/>            |
|   | Nasal                                | <input type="checkbox"/>            |
|   | Vaginal                              | <input type="checkbox"/>            |
|   | Rectal                               | <input type="checkbox"/>            |
|   | Intravenous                          | <input type="checkbox"/>            |
|   | Intravenous Bolus                    | <input type="checkbox"/>            |
|   | Intravenous Drip                     | <input type="checkbox"/>            |
|   | Other                                | <input type="checkbox"/>            |
| <hr/>   |                                      |                                     |
| If route of administration is Other, specify <input type="text"/> |                                      |                                     |
| <hr/>   |                                      |                                     |
| Start date (dd MMM yyyy)  | 28 AUG 2020                          |                                     |
| Start date completely unknown                                     | False                                |                                     |
| Ongoing?  | Yes <input type="checkbox"/>         | No <input checked="" type="radio"/> |
| <hr/>   |                                      |                                     |
| If not Ongoing, End date (dd MMM yyyy)                            | 29 AUG 2020                          |                                     |
| Was this medication taken for solicited event?                    | Yes <input type="checkbox"/>         | No <input checked="" type="radio"/> |
| <hr/>   |                                      |                                     |
| Separate Dosage Number (derived)                                  | 2                                    |                                     |
| Interval Dosage Unit Number (derived)                             | 1                                    |                                     |
| Interval Dosage Definition (derived)                              | 802 <input type="checkbox"/>         | 803 <input type="checkbox"/>        |
|   | 804 <input checked="" type="radio"/> |                                     |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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Name of Medication SPRINTEC  
(NORGESTIMATE/ETHINYL  
ESTRADIOL)

Prophylaxis Yes ☐  
No ☒

Indication UTERINE BLEEDING

Dose per administration 0.25/0.035

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☒

If frequency is Other, specify

TAKE 1 EVERY 6 HOURS X 4  
DAYS, THEN TAKE 1 EVERY 8  
HRS X 3 DAYS, THEN TAKE 1  
EVERY 12 HRS X 2 DAYS, THEN  
TAKE 1 DAILY

Route of administration Oral ☒

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:15

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Topical                  | <input type="checkbox"/>            |
|  | Subcutaneous             | <input type="checkbox"/>            |
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 29 AUG 2020              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 04 SEP 2020                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:15

|                                |  |
|--------------------------------|--|
| Name of Medication             | FERROUS SULPHATE   |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                     | FE DEFICIENCY ANEMIA   |
| Dose per administration        | 325  |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify |  |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input checked="" type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |  |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>  |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:15

|   |                          |                                  |
|---|--------------------------|----------------------------------|
|   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|   | Intralesional            | <input type="checkbox"/>         |
|   | Intraperitoneal          | <input type="checkbox"/>         |
|   | Nasal                    | <input type="checkbox"/>         |
|   | Vaginal                  | <input type="checkbox"/>         |
|   | Rectal                   | <input type="checkbox"/>         |
|   | Intravenous              | <input type="checkbox"/>         |
|   | Intravenous Bolus        | <input type="checkbox"/>         |
|   | Intravenous Drip         | <input type="checkbox"/>         |
|   | Other                    | <input type="checkbox"/>         |
| <hr/>   |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>   |                          |                                  |
| Start date (dd MMM yyyy)  |                          | 27 AUG 2020                      |
| Start date completely unknown                                     |                          | False                            |
| Ongoing?  | Yes                      | <input checked="" type="radio"/> |
|   | No                       | <input type="radio"/>            |
| <hr/>   |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>   |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|   | No                       | <input checked="" type="radio"/> |
| <hr/>   |                          |                                  |
| Separate Dosage Number (derived)                                  |                          | 3                                |
| Interval Dosage Unit Number (derived)                             |                          | 1                                |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|   | 803                      | <input type="radio"/>            |
|   | 804                      | <input checked="" type="radio"/> |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:15

|                                |   |
|--------------------------------|---|
| Name of Medication             | MOTRIN  |
| Prophylaxis                    | Yes <input type="checkbox"/><br>No <input checked="" type="checkbox"/>  |
| Indication                     | POSTOPERATIVE PAIN  |
| Dose per administration        | 800   |
| Dose unit                      | mg <input checked="" type="checkbox"/><br>ug <input type="checkbox"/><br>mL <input type="checkbox"/><br>g <input type="checkbox"/><br>IU <input type="checkbox"/><br>tablet <input type="checkbox"/><br>capsule <input type="checkbox"/><br>puff <input type="checkbox"/><br>Other <input type="checkbox"/>   |
| If dose unit is Other, specify |   |
| Frequency                      | once daily <input type="checkbox"/><br>twice daily <input type="checkbox"/><br>three times daily <input type="checkbox"/><br>four times daily <input type="checkbox"/><br>every other day <input type="checkbox"/><br>every week <input type="checkbox"/><br>every month <input type="checkbox"/><br>as needed <input checked="" type="checkbox"/><br>once <input type="checkbox"/><br>unknown <input type="checkbox"/><br>other <input type="checkbox"/> |
| If frequency is Other, specify |   |
| Route of administration        | Oral <input checked="" type="checkbox"/><br>Topical <input type="checkbox"/><br>Subcutaneous <input type="checkbox"/><br>Transdermal <input type="checkbox"/><br>Intraocular <input type="checkbox"/><br>Intramuscular <input type="checkbox"/>   |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:15

|   |                          |                                     |
|---|--------------------------|-------------------------------------|
|   | Respiratory (Inhalation) | <input type="checkbox"/>            |
|   | Intralesional            | <input type="checkbox"/>            |
|   | Intraperitoneal          | <input type="checkbox"/>            |
|   | Nasal                    | <input type="checkbox"/>            |
|   | Vaginal                  | <input type="checkbox"/>            |
|   | Rectal                   | <input type="checkbox"/>            |
|   | Intravenous              | <input type="checkbox"/>            |
|   | Intravenous Bolus        | <input type="checkbox"/>            |
|   | Intravenous Drip         | <input type="checkbox"/>            |
|   | Other                    | <input type="checkbox"/>            |
| <hr/>   |                          |                                     |
| If route of administration is Other, specify <input type="text"/> |                          |                                     |
| <hr/>   |                          |                                     |
| Start date (dd MMM yyyy)  |                          | 23 SEP 2020                         |
| Start date completely unknown                                     |                          | False                               |
| Ongoing?  | Yes                      | <input type="checkbox"/>            |
|   | No                       | <input checked="" type="checkbox"/> |
| <hr/>   |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)                            |                          | 07 OCT 2020                         |
| <hr/>   |                          |                                     |
| Was this medication taken for solicited event?                    | Yes                      | <input type="checkbox"/>            |
|   | No                       | <input checked="" type="checkbox"/> |
| <hr/>   |                          |                                     |
| Separate Dosage Number (derived)                                  |                          | <input type="text"/>                |
| Interval Dosage Unit Number (derived)                             |                          | <input type="text"/>                |
| Interval Dosage Definition (derived)                              |                          | 802 <input type="checkbox"/>        |
|   |                          | 803 <input type="checkbox"/>        |
|   |                          | 804 <input type="checkbox"/>        |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:15

|                                      |  |
|--------------------------------------|--|
| Name of Medication                   | COLACE   |
| Prophylaxis                          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| Indication                           | PREVENTION OF<br>CONSTIPATION WITH<br>POSTOPERATIVE OPIOID USE;<br>HYSTERECTOMY  |
| Dose per administration              | 100  |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify _____ |  |
| Frequency                            | once daily <input type="radio"/><br>twice daily <input checked="" type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |  |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/>  |

v6.020 DTW (1102)

383 of 2347



US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:15

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 23 SEP 2020              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 07 OCT 2020                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | 2                        |                                     |
| Interval Dosage Unit Number (derived)              | 1                        |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:46:15

|                                      |   |
|--------------------------------------|---|
| Name of Medication                   | ACETAMINOPHEN   |
| Prophylaxis                          | Yes <input type="checkbox"/><br>No <input checked="" type="checkbox"/>  |
| Indication                           | POSTOPERATIVE PAIN  |
| Dose per administration              | 325   |
| Dose unit                            | mg <input checked="" type="checkbox"/><br>ug <input type="checkbox"/><br>mL <input type="checkbox"/><br>g <input type="checkbox"/><br>IU <input type="checkbox"/><br>tablet <input type="checkbox"/><br>capsule <input type="checkbox"/><br>puff <input type="checkbox"/><br>Other <input type="checkbox"/>   |
| If dose unit is Other, specify _____ |   |
| Frequency                            | once daily <input type="checkbox"/><br>twice daily <input type="checkbox"/><br>three times daily <input type="checkbox"/><br>four times daily <input type="checkbox"/><br>every other day <input type="checkbox"/><br>every week <input type="checkbox"/><br>every month <input type="checkbox"/><br>as needed <input checked="" type="checkbox"/><br>once <input type="checkbox"/><br>unknown <input type="checkbox"/><br>other <input type="checkbox"/> |
| If frequency is Other, specify _____ |   |
| Route of administration              | Oral <input checked="" type="checkbox"/><br>Topical <input type="checkbox"/><br>Subcutaneous <input type="checkbox"/><br>Transdermal <input type="checkbox"/><br>Intraocular <input type="checkbox"/><br>Intramuscular <input type="checkbox"/>   |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:46:15

|   |                          |                                     |
|---|--------------------------|-------------------------------------|
|   | Respiratory (Inhalation) | <input type="checkbox"/>            |
|   | Intralesional            | <input type="checkbox"/>            |
|   | Intraperitoneal          | <input type="checkbox"/>            |
|   | Nasal                    | <input type="checkbox"/>            |
|   | Vaginal                  | <input type="checkbox"/>            |
|   | Rectal                   | <input type="checkbox"/>            |
|   | Intravenous              | <input type="checkbox"/>            |
|   | Intravenous Bolus        | <input type="checkbox"/>            |
|   | Intravenous Drip         | <input type="checkbox"/>            |
|   | Other                    | <input type="checkbox"/>            |
| <hr/>   |                          |                                     |
| If route of administration is Other, specify <input type="text"/> |                          |                                     |
| <hr/>   |                          |                                     |
| Start date (dd MMM yyyy)  |                          | 23 SEP 2020                         |
| Start date completely unknown                                     |                          | False                               |
| Ongoing?  | Yes                      | <input type="checkbox"/>            |
|   | No                       | <input checked="" type="checkbox"/> |
| <hr/>   |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)                            |                          | 07 OCT 2020                         |
| <hr/>   |                          |                                     |
| Was this medication taken for solicited event?                    | Yes                      | <input type="checkbox"/>            |
|   | No                       | <input checked="" type="checkbox"/> |
| <hr/>   |                          |                                     |
| Separate Dosage Number (derived)                                  |                          | <input type="text"/>                |
| Interval Dosage Unit Number (derived)                             |                          | <input type="text"/>                |
| Interval Dosage Definition (derived)                              |                          | 802 <input type="checkbox"/>        |
|   |                          | 803 <input type="checkbox"/>        |
|   |                          | 804 <input type="checkbox"/>        |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:46:15

|                                      |  |
|--------------------------------------|--|
| Name of Medication                   | NORCO<br>(HYDROCODONE/ACETAMINOPHEN)   |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                           | POSTOPERATIVE PAIN   |
| Dose per administration              | 5/325  |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify _____ |  |
| Frequency                            | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |  |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/>  |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:46:15

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 22 SEP 2020              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 07 OCT 2020                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:46:15

|                                      |  |
|--------------------------------------|--|
| Name of Medication                   | LEVONORGESTREL/ETHINYL<br>ESTRADIOL  |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                           | UTERINE BLEEDING   |
| Dose per administration              | 0.1/0.02   |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify _____ |  |
| Frequency                            | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |  |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/>   |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:46:15

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="radio"/>            |
|  | Respiratory (Inhalation) | <input type="radio"/>            |
|  | Intralesional            | <input type="radio"/>            |
|  | Intraperitoneal          | <input type="radio"/>            |
|  | Nasal                    | <input type="radio"/>            |
|  | Vaginal                  | <input type="radio"/>            |
|  | Rectal                   | <input type="radio"/>            |
|  | Intravenous              | <input type="radio"/>            |
|  | Intravenous Bolus        | <input type="radio"/>            |
|  | Intravenous Drip         | <input type="radio"/>            |
|  | Other                    | <input type="radio"/>            |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | 05 SEP 2020                      |
| Start date completely unknown                      |                          | False                            |
| Ongoing?   | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) 21 SEP 2020 |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   |                          | 1                                |
| Interval Dosage Unit Number (derived)              |                          | 1                                |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:46:15

|                                      |   |
|--------------------------------------|---|
| Name of Medication                   | AMOXICILLIN CLAVULANATE   |
| Prophylaxis                          | Yes <input type="checkbox"/><br>No <input checked="" type="checkbox"/>  |
| Indication                           | URINARY TRACT INFECTION   |
| Dose per administration              | 500/125   |
| Dose unit                            | mg <input checked="" type="checkbox"/><br>ug <input type="checkbox"/><br>mL <input type="checkbox"/><br>g <input type="checkbox"/><br>IU <input type="checkbox"/><br>tablet <input type="checkbox"/><br>capsule <input type="checkbox"/><br>puff <input type="checkbox"/><br>Other <input type="checkbox"/>   |
| If dose unit is Other, specify _____ |   |
| Frequency                            | once daily <input type="checkbox"/><br>twice daily <input checked="" type="checkbox"/><br>three times daily <input type="checkbox"/><br>four times daily <input type="checkbox"/><br>every other day <input type="checkbox"/><br>every week <input type="checkbox"/><br>every month <input type="checkbox"/><br>as needed <input type="checkbox"/><br>once <input type="checkbox"/><br>unknown <input type="checkbox"/><br>other <input type="checkbox"/> |
| If frequency is Other, specify _____ |   |
| Route of administration              | Oral <input checked="" type="checkbox"/><br>Topical <input type="checkbox"/><br>Subcutaneous <input type="checkbox"/><br>Transdermal <input type="checkbox"/><br>Intraocular <input type="checkbox"/><br>Intramuscular <input type="checkbox"/>   |



US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:46:15

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           |                          | 12 OCT 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 19 OCT 2020                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   |                          | 2                                   |
| Interval Dosage Unit Number (derived)              |                          | 1                                   |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:46:15

|                                |  |
|--------------------------------|--|
| Name of Medication             | FEXOFENADINE   |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                     | SEASONAL ALLERGIES   |
| Dose per administration        | 180  |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify |  |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |  |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>  |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:46:15

|   |                          |                                  |
|---|--------------------------|----------------------------------|
|   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|   | Intralesional            | <input type="checkbox"/>         |
|   | Intraperitoneal          | <input type="checkbox"/>         |
|   | Nasal                    | <input type="checkbox"/>         |
|   | Vaginal                  | <input type="checkbox"/>         |
|   | Rectal                   | <input type="checkbox"/>         |
|   | Intravenous              | <input type="checkbox"/>         |
|   | Intravenous Bolus        | <input type="checkbox"/>         |
|   | Intravenous Drip         | <input type="checkbox"/>         |
|   | Other                    | <input type="checkbox"/>         |
| <hr/>   |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>   |                          |                                  |
| Start date (dd MMM yyyy)  | UN                       | UNK 2010                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?  | Yes                      | <input checked="" type="radio"/> |
|   | No                       | <input type="radio"/>            |
| <hr/>   |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>   |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|   | No                       | <input checked="" type="radio"/> |
| <hr/>   |                          |                                  |
| Separate Dosage Number (derived)                                  | <input type="text"/>     |                                  |
| Interval Dosage Unit Number (derived)                             | <input type="text"/>     |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|   | 803                      | <input type="radio"/>            |
|   | 804                      | <input type="radio"/>            |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| Name of Medication  | PREDNISONE   |
| Prophylaxis   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication  | FOOT PAIN  |
| Dose per administration   | 4  |
| Dose unit   | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify  |  |
| Frequency   | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input checked="" type="radio"/> |
| If frequency is Other, specify  |  |
| TAPERED DOSE: 6 TODAY, 5<br>TOMORROW, 4 ON 30OCT, 3 ON<br>31OCT, 2 ON 1NOV, 1 ON 2NOV |  |
| Route of administration   | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/>  |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:46:15

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intraocular              | <input type="checkbox"/>         |
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | 28 OCT 2020              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | _____                    |                                  |
| Interval Dosage Unit Number (derived)              | _____                    |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:46:15

|                                |  |
|--------------------------------|--|
| Name of Medication             | INFLUENZA VACCINATION  |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| Indication                     | IMMUNIZATION   |
| Dose per administration        | 0.5  |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input checked="" type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify |  |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input checked="" type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |  |
| Route of administration        | Oral <input type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input checked="" type="radio"/>  |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:46:15

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           |                          | 14 OCT 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 14 OCT 2020                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:46:15

|                                |  |
|--------------------------------|--|
| Name of Medication             | FLUCONAZOLE (DIFLUCAN)   |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                     | VAGINAL CANDIDIASIS  |
| Dose per administration        | 150  |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify |  |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input checked="" type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |  |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>  |



US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:46:15

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           |                          | 20 OCT 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 20 OCT 2020                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:46:15

|                                |  |
|--------------------------------|--|
| Name of Medication             | NYSTATIN   |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                     | VAGINAL CANDIDIASIS  |
| Dose per administration        | 1  |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input checked="" type="radio"/>   |
| If dose unit is Other, specify | APPLICATION  |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |  |
| Route of administration        | Oral <input type="radio"/><br>Topical <input checked="" type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>  |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:46:15

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| <hr/>  |                          |                                  |
| If route of administration is Other, specify <hr/> |                          |                                  |
| Start date (dd MMM yyyy)                           | 28 OCT 2020              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| <hr/>  |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <hr/>       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| <hr/>  |                          |                                  |
| Separate Dosage Number (derived)                   | <hr/>                    |                                  |
| Interval Dosage Unit Number (derived)              | <hr/>                    |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

US3212013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:46:15

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3212013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:46:15

| Procedure/Surgery date ( <i>dd MMM<br/>yyyy</i> ) | Procedure/Surgery     | Indication      | If indication is Other, specify |
|---|-----------------------|-----------------|---------------------------------|
| 27 AUG 2020                                       | BLOOD TRANSFUSION     | Adverse Event   |                                 |
| 22 SEP 2020                                       | ELECTIVE HYSTERECTOMY | Medical History |                                 |

US3212013

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:46:15

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3212013

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:46:15

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:15

|  |   |
|--|---|
| SAEID  | USA-US115-2020-MRNA-1273-P301000003                           |
| Serious  | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death  | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening   | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity             | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                             | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event                                | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name                                      | VICKI   |
| Investigator's Last Name                                       | MILLER  |
| Site Address: Street   |   |
| Site Address: City   |   |
| Site Address: State  |   |
| Site Address: Postal Code                                      |   |
| Investigator Country   | US  |
| E2B Transmit Flag (Derived/Hidden)                             | 7   |



US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:46:15

|   |   |
|---|---|
| SAEID   | USA-US115-2020-MRNA-1273-P301000003                           |
| Serious   | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death   | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name   | VICKI   |
| Investigator's Last Name  | MILLER  |
| Site Address: Street  |   |
| Site Address: City  |   |
| Site Address: State   |   |
| Site Address: Postal Code   |   |
| Investigator Country  | US  |
| E2B Transmit Flag (Derived/Hidden)  | 7   |
| Date of submission (Pre-filled from custom function)  | 01/SEP/2020 11:51   |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True  |

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| SAEID   | USA-US115-2020-MRNA-1273-P301000003                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name   | VICKI  |
| Investigator's Last Name  | MILLER   |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   |  |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 7  |
| Date of submission (Pre-filled from custom function)  | 30/SEP/2020 15:29  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:46:15

|   |   |
|---|---|
| SAEID   | USA-US115-2020-MRNA-1273-P301000003                           |
| Serious   | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death   | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name   | VICKI   |
| Investigator's Last Name  | MILLER  |
| Site Address: Street  |   |
| Site Address: City  |   |
| Site Address: State   |   |
| Site Address: Postal Code   |   |
| Investigator Country  | US  |
| E2B Transmit Flag (Derived/Hidden)  | 7   |
| Date of submission (Pre-filled from custom function)  | 02/OCT/2020 08:31   |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True  |

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| SAEID   | USA-US115-2020-MRNA-1273-P301000003                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name   | VICKI  |
| Investigator's Last Name  | MILLER   |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   |  |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 7  |
| Date of submission (Pre-filled from custom function)  | 15/OCT/2020 20:34  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 10:46:15

|   |   |
|---|---|
| SAEID   | USA-US115-2020-MRNA-1273-P301000003                           |
| Serious   | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death   | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name   | VICKI   |
| Investigator's Last Name  | MILLER  |
| Site Address: Street  |   |
| Site Address: City  |   |
| Site Address: State   |   |
| Site Address: Postal Code   |   |
| Investigator Country  | US  |
| E2B Transmit Flag (Derived/Hidden)  | 7   |
| Date of submission (Pre-filled from custom function)  | 27/OCT/2020 10:30   |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True  |

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 10:46:15

|   |   |
|---|---|
| SAEID   | USA-US115-2020-MRNA-1273-P301000003                           |
| Serious   | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death   | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name   | VICKI   |
| Investigator's Last Name  | MILLER  |
| Site Address: Street  |   |
| Site Address: City  |   |
| Site Address: State   |   |
| Site Address: Postal Code   |   |
| Investigator Country  | US  |
| E2B Transmit Flag (Derived/Hidden)  | 7   |
| Date of submission (Pre-filled from custom function)  | 06/NOV/2020 11:16   |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True  |

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 10:46:15

|   |  |
|---|--|
| SAEID   | USA-US115-2020-MRNA-1273-P301000003                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name   | VICKI  |
| Investigator's Last Name  | MILLER   |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   |  |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 7  |
| Date of submission (Pre-filled from custom function)  | 24/NOV/2020 08:00  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:46:15

|  |   |
|--|---|
| SAEID  | USA-US115-2020-MRNA-1273-P301000005                           |
| Serious  | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death  | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening   | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity             | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                             | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event                                | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name                                      | VICKI   |
| Investigator's Last Name                                       | MILLER  |
| Site Address: Street   |   |
| Site Address: City   |   |
| Site Address: State  |   |
| Site Address: Postal Code                                      |   |
| Investigator Country   | US  |
| E2B Transmit Flag (Derived/Hidden)                             |   |



US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:46:15

|  |   |
|--|---|
| SAEID  | USA-US115-2020-MRNA-1273-P301000005                           |
| Serious  | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death  | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening   | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization   | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity   | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect   | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event  | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name  | VICKI   |
| Investigator's Last Name   | MILLER  |
| Site Address: Street   |   |
| Site Address: City   |   |
| Site Address: State  |   |
| Site Address: Postal Code  |   |
| Investigator Country   | US  |
| E2B Transmit Flag (Derived/Hidden)   |   |
| Date of submission (Pre-filled from custom function)   |   |
| <b>Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.</b> |   |

Audit

US3212013 (Prod: DM Clinical Research - ERN - PPDS)

**US3212013**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:46:15**

[Participant ID](#)

| Audit                    | User  | Time (GMT)           |
|--------------------------|---|----------------------|
| User entered 'US3212013' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 03 Aug 2020 20:24:19 |

**US3212013**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:46:15**

[Was this visit performed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 03 Aug 2020 20:25:45 |

**US3212013**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:46:15**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| User entered '03 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 03 Aug 2020 20:24:20 |

**US3212013**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:46:15**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 03 Aug 2020 20:25:45 |
|                                |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:46:15**

[Folder OID](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 03 Aug 2020 20:25:45 |

**US3212013**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:46:15**

[Date of Birth \(MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| User entered (b) (6) 1975' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 03 Aug 2020 20:24:21 |



**US3212013**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:46:15**

[Age](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| User entered '45' | (b) (4), (b) (6) | 03 Aug 2020 20:26:35 |
|                   |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:46:15**

[Age Units](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 03 Aug 2020 20:26:35 |

**US3212013**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:46:15**

[Age \(Derived\)](#)

| Audit             | User   | Time (GMT)           |
|-------------------|--------|----------------------|
| User entered '45' | System | 03 Aug 2020 20:27:34 |

**US3212013**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:46:15**

[Sex](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered 'Female (F)' | (b) (4), (b) (6) | 03 Aug 2020 20:26:35 |
|                           |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:46:15**

[Ethnicity](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4), (b) (6) | 03 Aug 2020 20:26:35 |

**US3212013**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:46:15**

[White](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '1' | (b) (4), (b) (6) | 03 Aug 2020 20:26:35 |
|                  |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:46:15**

[Black](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:26:35 |
|                  |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:46:15**

[Asian](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:26:35 |
|                  |                  |                      |



US3212013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:15

[American Indian or Alaska Native](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:26:35 |

US3212013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:15

[Native Hawaiian or other Pacific Islander](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:26:35 |

**US3212013**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:46:15**

[Other](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:26:35 |
|                  |                  |                      |

US3212013

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:46:15

If race is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 20:26:35 |

**US3212013**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:46:15**

[Unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:26:35 |
|                  |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:46:15**

[Not reported](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:26:35 |
|                  |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:46:15**

**Date of Informed Consent** (*dd MMM yyyy*)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered '3 Aug 2020' | (b) (4), (b) (6) | 03 Aug 2020 20:27:34 |

**US3212013**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:46:15**

[Month and Year of Informed Consent \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Aug 2020' | System | 03 Aug 2020 20:27:34 |



**US3212013**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:46:15**

[Year of Informed Consent \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 03 Aug 2020 20:27:34 |

**US3212013**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:46:15**

[Protocol Version](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| User entered 'Amendment 1 (1)' | (b) (4), (b) (6) | 03 Aug 2020 20:27:34 |

US3212013

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:46:15

[Was participant enrolled in the study?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 03 Aug 2020 20:27:34 |
|                        |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:46:15**

[If No, indicate reason for screen fail](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 20:27:34 |

US3212013

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:46:15

If reason for screen fail is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 20:27:34 |
|                     |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:46:15**

[Was this participant screened previously?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 20:27:34 |
|                       |                  |                      |

US3212013

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:46:15

[If Yes, previous participant number](#)

| Audit               | User  | Time (GMT)           |
|---------------------|---|----------------------|
| User entered empty. | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 03 Aug 2020 20:24:20 |

**US3212013**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:46:15**

[Enrollment Trigger](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Aug 2020 20:28:18 |



US3212013

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:46:15

Did the participant meet all eligibility criteria?

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 03 Aug 2020 20:28:18 |
|                        |                  |                      |

US3212013

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:46:15

[Were any significant conditions reported?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 03 Aug 2020 20:28:52 |
|                        |                  |                      |

US3212013

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:46:15

[Condition](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLG: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 03 Aug 2020 20:33:04 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4) | 03 Aug 2020 20:33:04 |
| Data point term sent to Coder  | System                          | 03 Aug 2020 20:31:44 |
| User entered 'Cesarean Section'  | (b) (4), (b) (6)                | 03 Aug 2020 20:31:21 |

**US3212013**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered '8 Dec 1993' | (b) (4), (b) (6) | 03 Aug 2020 20:31:21 |
|                           |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:31:21 |
|                  |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Condition ongoing at study entry](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 20:31:21 |

**US3212013**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:46:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered '8 Dec 1993' | (b) (4), (b) (6) | 03 Aug 2020 20:31:21 |
|                           |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:31:21 |



**US3212013**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Dec 1993' | System | 03 Aug 2020 20:31:21 |

**US3212013**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1993' | System | 03 Aug 2020 20:31:21 |

**US3212013**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Dec 1993' | System | 03 Aug 2020 20:31:21 |

**US3212013**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1993' | System | 03 Aug 2020 20:31:21 |

US3212013

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:46:15

[Condition](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLG: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)      | 03 Aug 2020 20:33:04 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)      | 03 Aug 2020 20:33:04 |
| Data point term sent to Coder  | System                               | 03 Aug 2020 20:32:46 |
| User entered 'Cesarean Section'  | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 03 Aug 2020 20:32:18 |

**US3212013**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '31 Aug 1998' | (b) (4), (b) (6) | 03 Aug 2020 20:32:18 |
|                            |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:32:18 |

**US3212013**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Condition ongoing at study entry](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 20:32:18 |
|                       |                  |                      |



**US3212013**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:46:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '31 Aug 1998' | (b) (4), (b) (6) | 03 Aug 2020 20:32:18 |
|                            |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:32:18 |

**US3212013**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Aug 1998' | System | 03 Aug 2020 20:32:18 |

**US3212013**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1998' | System | 03 Aug 2020 20:32:18 |

**US3212013**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Aug 1998' | System | 03 Aug 2020 20:32:18 |

**US3212013**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1998' | System | 03 Aug 2020 20:32:18 |

US3212013

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:46:15

[Condition](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLG: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)      | 03 Aug 2020 20:35:06 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)      | 03 Aug 2020 20:35:06 |
| Data point term sent to Coder  | System                               | 03 Aug 2020 20:33:49 |
| User entered 'Cesarean Section'  | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 03 Aug 2020 20:33:48 |

**US3212013**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '25 Jun 2002' | (b) (4), (b) (6) | 03 Aug 2020 20:33:48 |
|                            |                  |                      |



**US3212013**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:33:48 |

**US3212013**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Condition ongoing at study entry](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 20:33:48 |

**US3212013**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:46:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '25 Jun 2002' | (b) (4), (b) (6) | 03 Aug 2020 20:33:48 |
|                            |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:33:48 |

**US3212013**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jun 2002' | System | 03 Aug 2020 20:33:48 |

**US3212013**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2002' | System | 03 Aug 2020 20:33:48 |

**US3212013**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jun 2002' | System | 03 Aug 2020 20:33:48 |

**US3212013**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2002' | System | 03 Aug 2020 20:33:48 |



US3212013

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:46:15

[Condition](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Aug 2020 20:35:07 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4) | 03 Aug 2020 20:35:07 |
| Data point term sent to Coder  | System               | 03 Aug 2020 20:34:49 |
| User entered 'Cholecystectomy'   | (b) (4), (b) (6)     | 03 Aug 2020 20:34:40 |

**US3212013**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2016' | (b) (4), (b) (6) | 03 Aug 2020 20:34:40 |
|                            |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:34:40 |
|                  |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Condition ongoing at study entry](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 20:34:40 |
|                       |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:46:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2016' | (b) (4), (b) (6) | 03 Aug 2020 20:34:40 |
|                            |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:34:40 |

**US3212013**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2016' | System | 03 Aug 2020 20:34:40 |

**US3212013**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2016' | System | 03 Aug 2020 20:34:40 |



**US3212013**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2016' | System | 03 Aug 2020 20:34:40 |

**US3212013**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2016' | System | 03 Aug 2020 20:34:40 |

US3212013

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:46:15

[Condition](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Aug 2020 20:37:08 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4) | 03 Aug 2020 20:37:08 |
| Data point term sent to Coder  | System               | 03 Aug 2020 20:35:50 |
| User entered 'Cholelithiasis'  | (b) (4), (b) (6)     | 03 Aug 2020 20:35:35 |

**US3212013**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2016' | (b) (4), (b) (6) | 03 Aug 2020 20:35:35 |
|                            |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:35:35 |

**US3212013**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Condition ongoing at study entry](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 20:35:35 |

**US3212013**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:46:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2016' | (b) (4), (b) (6) | 03 Aug 2020 20:35:35 |
|                            |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:35:35 |



**US3212013**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2016' | System | 03 Aug 2020 20:35:35 |

**US3212013**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2016' | System | 03 Aug 2020 20:35:35 |

**US3212013**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2016' | System | 03 Aug 2020 20:35:35 |

**US3212013**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2016' | System | 03 Aug 2020 20:35:35 |

US3212013

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:46:15

[Condition](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)      | 03 Aug 2020 20:37:08 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)      | 03 Aug 2020 20:37:08 |
| Data point term sent to Coder  | System                               | 03 Aug 2020 20:36:51 |
| User entered 'Bilateral Tubal Ligation'  | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 03 Aug 2020 20:36:29 |

**US3212013**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '25 Jun 2002' | (b) (4), (b) (6) | 03 Aug 2020 20:36:29 |
|                            |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:36:29 |

**US3212013**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Condition ongoing at study entry](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 20:36:29 |
|                       |                  |                      |



**US3212013**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:46:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '25 Jun 2002' | (b) (4), (b) (6) | 03 Aug 2020 20:36:29 |
|                            |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:36:29 |

**US3212013**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jun 2002' | System | 03 Aug 2020 20:36:29 |

**US3212013**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2002' | System | 03 Aug 2020 20:36:29 |

**US3212013**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jun 2002' | System | 03 Aug 2020 20:36:29 |

**US3212013**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2002' | System | 03 Aug 2020 20:36:29 |

US3212013

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:46:15

Condition

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Aug 2020 20:47:08 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4) | 03 Aug 2020 20:47:08 |
| Data point term sent to Coder  | System               | 03 Aug 2020 20:45:56 |
| User entered 'Seasonal Allergies'  | (b) (4), (b) (6)     | 03 Aug 2020 20:45:22 |

**US3212013**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2010' | (b) (4), (b) (6) | 03 Aug 2020 20:45:22 |



**US3212013**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:45:22 |
|                  |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 03 Aug 2020 20:45:22 |
|                        |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:46:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 20:45:22 |
|                     |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:45:22 |
|                  |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2010' | System | 03 Aug 2020 20:45:22 |

**US3212013**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2010' | System | 03 Aug 2020 20:45:22 |

**US3212013**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 03 Aug 2020 20:45:22 |

**US3212013**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 03 Aug 2020 20:45:22 |



US3212013

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:46:15

[Condition](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Iron deficiency anaemia, LLT: Iron deficiency anemia - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 26 Oct 2020 20:32:27 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4) | 26 Oct 2020 20:32:27 |
| Data point term sent to Coder   | System                          | 26 Oct 2020 20:31:22 |
| Coding entries removed.   | Afifah Ayub (b) (4)<br>(b) (4)  | 26 Oct 2020 20:30:52 |
| User entered 'IRON DEFICIENCY anemia' reason for change: Data Entry Error   | Afifah Ayub (b) (4)<br>(b) (4)  | 26 Oct 2020 20:30:52 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Iron and trace metal metabolism disorders, HLT: Iron deficiencies, PT: Iron deficiency, LLT: Iron deficiency - version MedDRA\\23.0.                        | Coder Import (b) (4)<br>(b) (4) | 03 Aug 2020 20:47:08 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4) | 03 Aug 2020 20:47:08 |
| Data point term sent to Coder   | System                          | 03 Aug 2020 20:45:57 |
| User entered 'Iron Deficiency'  | (b) (4), (b) (6)<br>(b) (4)     | 03 Aug 2020 20:45:45 |

**US3212013**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2018' | (b) (4), (b) (6) | 03 Aug 2020 20:45:45 |
|                            |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:45:45 |

**US3212013**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Condition ongoing at study entry](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 03 Aug 2020 20:49:54 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 03 Aug 2020 20:49:54 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | (b) (4), (b) (6) | 03 Aug 2020 20:49:54 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 03 Aug 2020 20:45:45 |
| User entered empty.  | (b) (4), (b) (6) | 03 Aug 2020 20:45:45 |

**US3212013**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:46:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 20:45:45 |
|                     |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:45:45 |

**US3212013**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2018' | System | 03 Aug 2020 20:45:45 |

**US3212013**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2018' | System | 03 Aug 2020 20:45:45 |



**US3212013**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 03 Aug 2020 20:45:45 |

**US3212013**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 03 Aug 2020 20:45:45 |

US3212013

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:46:15

Condition

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 03 Aug 2020 20:47:08 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4) | 03 Aug 2020 20:47:08 |
| Data point term sent to Coder   | System                          | 03 Aug 2020 20:46:58 |
| User entered 'Gastroesophageal Reflux Disease'  | (b) (4), (b) (6)                | 03 Aug 2020 20:46:11 |

**US3212013**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2017' | (b) (4), (b) (6) | 03 Aug 2020 20:46:11 |
|                            |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:46:11 |

**US3212013**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Condition ongoing at study entry](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 03 Aug 2020 20:46:26 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 03 Aug 2020 20:46:26 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | (b) (4), (b) (6) | 03 Aug 2020 20:46:26 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 03 Aug 2020 20:46:11 |
| User entered empty.  | (b) (4), (b) (6) | 03 Aug 2020 20:46:11 |

**US3212013**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:46:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 20:46:11 |
|                     |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:46:11 |



**US3212013**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2017' | System | 03 Aug 2020 20:46:11 |

**US3212013**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2017' | System | 03 Aug 2020 20:46:11 |

**US3212013**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 03 Aug 2020 20:46:11 |

**US3212013**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 03 Aug 2020 20:46:11 |

US3212013

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:46:15

Condition

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary incontinence, LLT: Urinary incontinence - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 03 Aug 2020 20:49:09 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4) | 03 Aug 2020 20:49:09 |
| Data point term sent to Coder  | System                          | 03 Aug 2020 20:48:03 |
| User entered 'Urinary Incontinence'  | (b) (4), (b) (6)<br>(b) (4)     | 03 Aug 2020 20:47:09 |

**US3212013**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2019' | (b) (4), (b) (6) | 03 Aug 2020 20:47:09 |
|                            |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:47:09 |

US3212013

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:46:15

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 03 Aug 2020 20:47:09 |
|                        |                  |                      |



**US3212013**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:46:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 20:47:09 |
|                     |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:47:09 |

**US3212013**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2019' | System | 03 Aug 2020 20:47:09 |

**US3212013**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2019' | System | 03 Aug 2020 20:47:09 |

**US3212013**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 03 Aug 2020 20:47:09 |

**US3212013**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 03 Aug 2020 20:47:09 |

**US3212013**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:46:15**

[Condition](#)

| Audit                         | User             | Time (GMT)           |
|-------------------------------|------------------|----------------------|
| Data point term sent to Coder | System           | 03 Aug 2020 20:48:01 |
| User entered 'Peroneal Tear'  | (b) (4), (b) (6) | 03 Aug 2020 20:47:46 |
|                               |                  |                      |

US3212013

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:46:15

[Start date \(dd MMM yyyy\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System). | System           | 03 Aug 2020 20:48:46 |
| User entered 'UN Feb 2020' reason for change: Data Entry Error   | (b) (4), (b) (6) | 03 Aug 2020 20:48:46 |
| User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System). | System           | 03 Aug 2020 20:47:46 |
| User entered empty.  | (b) (4), (b) (6) | 03 Aug 2020 20:47:46 |



**US3212013**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:47:46 |

US3212013

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:46:15

[Condition ongoing at study entry](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System). | System           | 03 Aug 2020 20:48:46 |
| User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System). | System           | 03 Aug 2020 20:47:46 |
| User entered 'No (N)'  | (b) (4), (b) (6) | 03 Aug 2020 20:47:46 |

**US3212013**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:46:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'UN Feb 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 03 Aug 2020 20:48:46 |
| User entered empty.  | (b) (4), (b) (6) | 03 Aug 2020 20:47:46 |

**US3212013**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:47:46 |

**US3212013**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Feb 2020' | System | 03 Aug 2020 20:48:46 |
| User entered empty.     | System | 03 Aug 2020 20:47:46 |

**US3212013**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 03 Aug 2020 20:48:46 |
| User entered empty. | System | 03 Aug 2020 20:47:46 |

**US3212013**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Feb 2020' | System | 03 Aug 2020 20:48:46 |
| User entered empty.     | System | 03 Aug 2020 20:47:46 |

**US3212013**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 03 Aug 2020 20:48:46 |
| User entered empty. | System | 03 Aug 2020 20:47:46 |



US3212013

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:46:15

[Condition](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLG: Soft tissue therapeutic procedures, HLT: Tendon therapeutic procedures, PT: Tenoplasty, LLT: Tendon repair - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 08 Sep 2020 13:30:51 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4) | 08 Sep 2020 13:30:51 |
| Data point term sent to Coder  | System                          | 03 Aug 2020 20:50:04 |
| User entered 'Peroneal Tendon Repair'  | (b) (4), (b) (6)<br>(b) (4)     | 03 Aug 2020 20:49:30 |

US3212013

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:46:15

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN Feb 2020' | (b) (4), (b) (6) | 03 Aug 2020 20:49:30 |

**US3212013**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:49:30 |

**US3212013**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:46:15**

[Condition ongoing at study entry](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 20:49:30 |

**US3212013**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:46:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'UN Feb 2020' | (b) (4), (b) (6) | 03 Aug 2020 20:49:30 |
|                            |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:49:30 |

**US3212013**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Feb 2020' | System | 03 Aug 2020 20:49:30 |

**US3212013**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 03 Aug 2020 20:49:30 |



**US3212013**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Feb 2020' | System | 03 Aug 2020 20:49:30 |

**US3212013**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 03 Aug 2020 20:49:30 |

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:46:15

Condition

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 17 Nov 2020 07:49:57 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4) | 17 Nov 2020 07:49:57 |
| Data point term sent to Coder  | System                          | 26 Oct 2020 20:31:22 |
| Coding entries removed.  | Afifah Ayub (b) (4)<br>(b) (4)  | 26 Oct 2020 20:30:32 |
| User entered 'intramural UTERINE FIBROIDS' reason for change: Data Entry Error   | Afifah Ayub (b) (4)<br>(b) (4)  | 26 Oct 2020 20:30:32 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 29 Sep 2020 19:45:38 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4) | 29 Sep 2020 19:45:38 |
| Data point term sent to Coder  | System                          | 29 Sep 2020 19:44:23 |
| User entered 'Uterine fibroids'  | Afifah Ayub (b) (4)<br>(b) (4)  | 29 Sep 2020 19:43:33 |
| DataPoint activated with code reason code Data required.   | Afifah Ayub (b) (4)<br>(b) (4)  | 29 Sep 2020 19:43:18 |
| DataPoint inactivated with code reason code Data not required.   | Afifah Ayub (b) (4)<br>(b) (4)  | 20 Aug 2020 17:32:07 |

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:46:15

[Start date \(dd MMM yyyy\)](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered 'UN UNK 2012'                                     | Afifah Ayub (b) (4)            | 29 Sep 2020 19:43:33 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>Afifah Ayub (b) (4) | 29 Sep 2020 19:43:18 |
| DataPoint inactivated with code reason code Data not required. | Afifah Ayub (b) (4)<br>(b) (4) | 20 Aug 2020 17:32:07 |

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:46:15

[Start date completely unknown](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered '0'   | Afifah Ayub (b) (4)            | 29 Sep 2020 19:43:33 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>Afifah Ayub (b) (4) | 29 Sep 2020 19:43:18 |
| DataPoint inactivated with code reason code Data not required. | Afifah Ayub (b) (4)<br>(b) (4) | 20 Aug 2020 17:32:07 |

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:46:15

[Condition ongoing at study entry](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error      | Afifah Ayub (b) (4) | 26 Oct 2020 20:30:32 |
| User entered 'Yes (Y)'   | Afifah Ayub (b) (4) | 29 Sep 2020 19:43:33 |
| DataPoint activated with code reason code Data required.       | Afifah Ayub (b) (4) | 29 Sep 2020 19:43:18 |
| DataPoint inactivated with code reason code Data not required. | Afifah Ayub (b) (4) | 20 Aug 2020 17:32:07 |

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:46:15

If No, please specify the stop date (dd MMM yyyy)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User entered '22 Sep 2020' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 26 Oct 2020 20:30:32 |
| User entered empty.  | Afifah Ayub (b) (4) | 29 Sep 2020 19:43:33 |
| DataPoint activated with code reason code Data required.       | Afifah Ayub (b) (4) | 29 Sep 2020 19:43:18 |
| DataPoint inactivated with code reason code Data not required. | Afifah Ayub (b) (4) | 20 Aug 2020 17:32:07 |

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:46:15

[Stop date completely unknown](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered '0'   | Afifah Ayub (b) (4)            | 29 Sep 2020 19:43:33 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>Afifah Ayub (b) (4) | 29 Sep 2020 19:43:18 |
| DataPoint inactivated with code reason code Data not required. | Afifah Ayub (b) (4)<br>(b) (4) | 20 Aug 2020 17:32:07 |



US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:46:15

[Start Month and Year \(derived\)](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered 'Jan 2012'  | System                         | 29 Sep 2020 19:43:33 |
| DataPoint activated with code reason code Data required.       | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 19:43:18 |
| DataPoint inactivated with code reason code Data not required. | Afifah Ayub (b) (4)<br>(b) (4) | 20 Aug 2020 17:32:07 |

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:46:15

[Start Year \(derived\)](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered '2012'  | System                         | 29 Sep 2020 19:43:33 |
| DataPoint activated with code reason code Data required.       | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 19:43:18 |
| DataPoint inactivated with code reason code Data not required. | Afifah Ayub (b) (4)<br>(b) (4) | 20 Aug 2020 17:32:07 |

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:46:15

[Stop Month and Year \(derived\)](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered 'Sep 2020'  | System                         | 26 Oct 2020 20:30:32 |
| User entered empty.  | System                         | 29 Sep 2020 19:43:33 |
| DataPoint activated with code reason code Data required.       | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 19:43:18 |
| DataPoint inactivated with code reason code Data not required. | Afifah Ayub (b) (4)<br>(b) (4) | 20 Aug 2020 17:32:07 |

**US3212013**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Year \(derived\)](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User entered '2020'  | System              | 26 Oct 2020 20:30:32 |
| User entered empty.  | System              | 29 Sep 2020 19:43:33 |
| DataPoint activated with code reason code Data required.       | Afifah Ayub (b) (4) | 29 Sep 2020 19:43:18 |
| DataPoint inactivated with code reason code Data not required. | Afifah Ayub (b) (4) | 20 Aug 2020 17:32:07 |

US3212013

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:46:15

Condition

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 29 Sep 2020 19:46:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4) | 29 Sep 2020 19:46:42 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 29 Sep 2020 19:45:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4) | 29 Sep 2020 19:45:39 |
| Data point term sent to Coder   | System                          | 29 Sep 2020 19:45:27 |
| DataPoint activated with code reason code Data required.  | Afifah Ayub (b) (4)<br>(b) (4)  | 29 Sep 2020 19:44:47 |
| DataPoint inactivated with code reason code Data not required.  | Afifah Ayub (b) (4)<br>(b) (4)  | 29 Sep 2020 19:44:32 |
| Data point term sent to Coder   | System                          | 29 Sep 2020 19:44:23 |
| User entered 'Obesity'  | Afifah Ayub (b) (4)<br>(b) (4)  | 29 Sep 2020 19:43:44 |

US3212013

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:46:15

Start date (dd MMM yyyy)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User closed query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day. please review and update as per CCGs page 22. Thank you' (Site from DM).   | (b) (4), (b) (6)               | 15 Nov 2020 18:45:21 |
| Query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day. please review and update as per CCGs page 22. Thank you' answered with 'subject diagnosed with obesity at screening visit. data correct as entered.' (Site from DM). | Reagan Reed (b) (4)<br>(b) (4) | 16 Oct 2020 21:03:59 |
| User opened query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day. please review and update as per CCGs page 22. Thank you' (Site from DM).   | (b) (4), (b) (6)               | 14 Oct 2020 22:08:14 |
| DataPoint activated with code reason code Data required.  | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 19:44:47 |
| DataPoint inactivated with code reason code Data not required.  | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 19:44:32 |
| User entered '03 Aug 2020'  | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 19:43:44 |

**US3212013**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| DataPoint activated with code reason code Data required.       | Afifah Ayub (b) (4) | 29 Sep 2020 19:44:47 |
| DataPoint inactivated with code reason code Data not required. | Afifah Ayub (b) (4) | 29 Sep 2020 19:44:32 |
| User entered '0'   | Afifah Ayub (b) (4) | 29 Sep 2020 19:43:44 |

US3212013

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:46:15

[Condition ongoing at study entry](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| DataPoint activated with code reason code Data required.       | Afifah Ayub (b) (4) | 29 Sep 2020 19:44:47 |
| DataPoint inactivated with code reason code Data not required. | Afifah Ayub (b) (4) | 29 Sep 2020 19:44:32 |
| User entered 'Yes (Y)'   | Afifah Ayub (b) (4) | 29 Sep 2020 19:43:44 |



**US3212013**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:46:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| DataPoint activated with code reason code Data required.       | Afifah Ayub (b) (4) | 29 Sep 2020 19:44:47 |
| DataPoint inactivated with code reason code Data not required. | Afifah Ayub (b) (4) | 29 Sep 2020 19:44:32 |
| User entered empty.  | Afifah Ayub (b) (4) | 29 Sep 2020 19:43:44 |

US3212013

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:46:15

[Stop date completely unknown](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| DataPoint activated with code reason code Data required.       | Afifah Ayub (b) (4) | 29 Sep 2020 19:44:47 |
| DataPoint inactivated with code reason code Data not required. | Afifah Ayub (b) (4) | 29 Sep 2020 19:44:32 |
| User entered '0'   | Afifah Ayub (b) (4) | 29 Sep 2020 19:43:44 |

US3212013

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:46:15

[Start Month and Year \(derived\)](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| DataPoint activated with code reason code Data required.       | Afifah Ayub (b) (4) | 29 Sep 2020 19:44:47 |
| DataPoint inactivated with code reason code Data not required. | Afifah Ayub (b) (4) | 29 Sep 2020 19:44:32 |
| User entered 'Aug 2020'  | System              | 29 Sep 2020 19:43:44 |

**US3212013**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:46:15**

[Start Year \(derived\)](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| DataPoint activated with code reason code Data required.       | Afifah Ayub (b) (4) | 29 Sep 2020 19:44:47 |
| DataPoint inactivated with code reason code Data not required. | Afifah Ayub (b) (4) | 29 Sep 2020 19:44:32 |
| User entered '2020'  | System              | 29 Sep 2020 19:43:44 |

US3212013

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:46:15

[Stop Month and Year \(derived\)](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| DataPoint activated with code reason code Data required.       | Afifah Ayub (b) (4) | 29 Sep 2020 19:44:47 |
| DataPoint inactivated with code reason code Data not required. | Afifah Ayub (b) (4) | 29 Sep 2020 19:44:32 |
| User entered empty.  | System              | 29 Sep 2020 19:43:44 |

**US3212013**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:46:15**

[Stop Year \(derived\)](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| DataPoint activated with code reason code Data required.       | Afifah Ayub (b) (4) | 29 Sep 2020 19:44:47 |
| DataPoint inactivated with code reason code Data not required. | Afifah Ayub (b) (4) | 29 Sep 2020 19:44:32 |
| User entered empty.  | System              | 29 Sep 2020 19:43:44 |

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

[Were vital signs assessed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 03 Aug 2020 20:55:19 |

**US3212013**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

**Date of assessment** (*dd MMM yyyy*)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered '3 Aug 2020' | (b) (4), (b) (6) | 03 Aug 2020 20:55:19 |



**US3212013**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

**Time of assessment (00:00-23:59)**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| User entered '14:06' | (b) (4), (b) (6) | 03 Aug 2020 20:55:19 |

**US3212013**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '3 Aug 2020 14:06' | System | 03 Aug 2020 20:55:19 |

**US3212013**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Height \(xxx.x\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered '62' in      | (b) (4), (b) (6) | 03 Aug 2020 20:55:19 |
| DataPoint set to visible. | System           | 03 Aug 2020 20:28:18 |

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

[Weight \(xxx.x\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered '200' lb     | (b) (4), (b) (6) | 03 Aug 2020 20:55:19 |
| DataPoint set to visible. | System           | 03 Aug 2020 20:28:18 |

**US3212013**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

**BMI (xxx.x)**

| Audit                                      | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: User entered '36.65696' | System | 16 Sep 2020 23:41:44 |
| User entered '36.7'                        | System | 03 Aug 2020 20:55:19 |
| DataPoint set to visible.                  | System | 03 Aug 2020 20:28:18 |

**US3212013**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[BMI units](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--------|----------------------|
| User entered 'kg/m2'      | System | 03 Aug 2020 20:55:19 |
| DataPoint set to visible. | System | 03 Aug 2020 20:28:18 |

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

Temperature (xxx.x)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Afifah Ayub (b) (4) | 20 Aug 2020 17:32:49 |
| User entered '97.4' F   | (b) (4), (b) (6)    | 03 Aug 2020 20:55:19 |

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

[Route of measurement](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User entered empty; reason for change Data Entry Error           | Afifah Ayub (b) (4) | 07 Oct 2020 17:02:48 |
| User entered 'Other (Other)' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 20 Aug 2020 17:32:49 |
| User entered 'Oral (Oral)'                                       | (b) (4), (b) (6)    | 03 Aug 2020 20:55:19 |



US3212013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

[If Other, specify](#)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| User entered empty; reason for change Data Entry Error                      | Afifah Ayub (b) (4) | 07 Oct 2020 17:02:48 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Afifah Ayub (b) (4) | 20 Aug 2020 17:32:49 |
| User entered empty.   | (b) (4), (b) (6)    | 03 Aug 2020 20:55:19 |

**US3212013**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Pulse \(xxx\)](#)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Afifah Ayub (b) (4) | 20 Aug 2020 17:32:49 |
| User entered '68'   | (b) (4), (b) (6)    | 03 Aug 2020 20:55:19 |

**US3212013**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 03 Aug 2020 20:55:19 |

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

[Respiratory Rate \(xxx\)](#)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Afifah Ayub (b) (4) | 20 Aug 2020 17:32:49 |
| User entered '12'   | (b) (4), (b) (6)    | 03 Aug 2020 20:55:19 |

**US3212013**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 03 Aug 2020 20:55:19 |

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

Systolic Blood Pressure (xxx)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Afifah Ayub (b) (4) | 20 Aug 2020 17:32:49 |
| User entered '142'  | (b) (4), (b) (6)    | 03 Aug 2020 20:55:19 |

**US3212013**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 03 Aug 2020 20:55:19 |

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

Diastolic Blood Pressure (xxx)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Afifah Ayub (b) (4) | 20 Aug 2020 17:32:49 |
| User entered '92'   | (b) (4), (b) (6)    | 03 Aug 2020 20:55:19 |



**US3212013**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 03 Aug 2020 20:55:19 |

US3212013

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:15

Was the physical examination performed?

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 03 Aug 2020 20:56:00 |
|                        |                  |                      |

US3212013

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:15

Date of examination (dd MMM yyyy)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).    | (b) (4), (b) (6) | 07 Sep 2020 09:25:44 |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). |                  | 02 Sep 2020 17:13:23 |
| User entered '3 Aug 2020'  | (b) (4), (b) (6) | 03 Aug 2020 20:56:00 |

**US3212013**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:46:15**

**Date of assessment** (*dd MMM yyyy*)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered '3 Aug 2020' | (b) (4), (b) (6) | 03 Aug 2020 20:57:53 |
|                           |                  |                      |

US3212013

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:46:15

Is the participant of childbearing potential?

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 20:57:53 |
|                       |                  |                      |

US3212013

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:46:15

[If No, what is the reason?](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System). | System           | 03 Aug 2020 21:00:19 |
| User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System). | System           | 03 Aug 2020 20:57:53 |
| User entered 'Surgically sterile (SURGICALLY STERILE)'  | (b) (4), (b) (6) | 03 Aug 2020 20:57:53 |

US3212013

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:46:15

If Partner medically sterile or Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 20:57:53 |
|                     |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:46:15**

**If Surgically sterile, date of surgery (*dd MMM yyyy*)**

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '25 Jun 2002' | (b) (4), (b) (6) | 03 Aug 2020 20:57:53 |



US3212013

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:46:15

Date of surgery unknown

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:57:53 |
|                  |                  |                      |

US3212013

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:46:15

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System           | 03 Aug 2020 21:00:48 |
| User entered empty; reason for change Data Entry Error                                  | (b) (4), (b) (6) | 03 Aug 2020 21:00:48 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System           | 03 Aug 2020 21:00:19 |
| User entered 'UN UNK ' (non-conformant).  | (b) (4), (b) (6) | 03 Aug 2020 21:00:19 |
| User entered '1 Aug 2020'   | (b) (4), (b) (6) | 03 Aug 2020 20:57:53 |

US3212013

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:46:15

[Date of last menstruation unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 20:57:53 |
|                  |                  |                      |

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |
|                        |                  |                      |

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |
|                       |                  |                      |

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |
|                       |                  |                      |



US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |
|                       |                  |                      |

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |
|                       |                  |                      |

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |
|                       |                  |                      |

**US3212013**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:46:15**

**Other**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

[Specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |



US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

No Risk Identified

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |
|                  |                  |                      |

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '1' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |
|                  |                  |                      |

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |
|                  |                  |                      |

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

[Resides in a single family home](#) (i.e., detached housing)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |

**US3212013**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:46:15**

**Other**

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered 'I' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:46:15

[Specify](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User entered 'Participant lives with children in the household likely to go back to school in person this year' | (b) (4), (b) (6) | 03 Aug 2020 21:03:58 |



US3212013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:46:15

[Was this visit performed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 03 Aug 2020 21:05:43 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:46:15**

[Visit date \(dd MMM yyyy\)](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User entered '03 Aug 2020' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 10 Nov 2020 14:03:25 |
| User entered '3 Aug 2020'                                      | (b) (4), (b) (6)    | 03 Aug 2020 21:05:43 |

US3212013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:46:15

Was visit performed at the participant's home or at the clinic?

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 03 Aug 2020 21:05:43 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:46:15**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 03 Aug 2020 21:05:43 |

US3212013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:46:15

What was the date of randomization? (*dd MMM yyyy*)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| User entered '03 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 03 Aug 2020 20:24:25 |

US3212013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:46:15

What was the participant's randomization number?

| Audit  | User   | Time (GMT)           |
|--|--|----------------------|
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System   | 21 Aug 2020 01:49:41 |
| Amendment Manager: Data point set to conformant.   | System   | 21 Aug 2020 01:49:40 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System).                    | System   | 03 Aug 2020 20:24:25 |
| User entered '100752' (non-conformant).  | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 03 Aug 2020 20:24:25 |

US3212013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:46:15

[In what Cohort was the participant enrolled?](#)

| Audit   | User   | Time (GMT)           |
|---|--|----------------------|
| User entered '>=18 and <65 years and not at risk (1)' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 03 Aug 2020 20:24:25 |

US3212013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:46:15

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:08:59 |



**US3212013**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:46:15**

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:08:59 |

US3212013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:46:15

Severe obesity (body mass index > or = 40kg/m2

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:08:59 |
|                       |                  |                      |

US3212013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:46:15

Diabetes (Type I, Type 2, or gestational)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:08:59 |

US3212013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:46:15

[Liver Disease](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:08:59 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:46:15

Height

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered missing code ND - Not Done. | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:46:15

Weight

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered missing code ND - Not Done. | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:46:15

Height

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered missing code ND - Not Done. | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:46:15

Weight

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered missing code ND - Not Done. | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |



US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

[Timepoint](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

Were vital signs assessed?

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| User entered '3 Aug 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:46:15**

**Time of assessment (00:00-23:59)**

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| User entered '14:06' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '3 Aug 2020 14:06' | System | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

Temperature (xxx.x)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered '97.4' F | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

[Route of measurement](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (Oral)' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:46:15**

[If Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |



US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

Pulse (xxx)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '68' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

[Respiratory Rate \(xxx\)](#)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '12' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

Systolic Blood Pressure (xxx)

| Audit              | User                           | Time (GMT)           |
|--------------------|--------------------------------|----------------------|
| User entered '142' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

Diastolic Blood Pressure (xxx)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '92' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 04 Aug 2020 13:20:40 |



US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:46:15

Height

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered missing code ND - Not Done. | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:46:15

Weight

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered missing code ND - Not Done. | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

[Timepoint](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

Were vital signs assessed?

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| User entered '3 Aug 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

Time of assessment (00:00-23:59)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).   | (b) (4), (b) (6)               | 06 Aug 2020 11:03:20 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'As per protocol, post-dose vitals are done at 30 minutes.' (Site from System). | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 14:27:15 |
| User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).   |                                | 04 Aug 2020 13:20:40 |
| User entered '16:52'   | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '3 Aug 2020 16:52' | System | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

Temperature (xxx.x)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered '97.1' F | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |



US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

[Route of measurement](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (Oral)' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

[If Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

Pulse (xxx)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '76' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

[Respiratory Rate \(xxx\)](#)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '16' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

Systolic Blood Pressure (xxx)

| Audit              | User                           | Time (GMT)           |
|--------------------|--------------------------------|----------------------|
| User entered '132' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 04 Aug 2020 13:20:40 |



US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

Diastolic Blood Pressure (xxx)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '84' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:20:40 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 04 Aug 2020 13:20:40 |

US3212013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:15

[Was the physical examination performed?](#)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 20 Aug 2020 17:33:31 |
| User entered 'Yes (Y)'                                    | Afifah Ayub (b) (4) | 04 Aug 2020 13:17:43 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:46:15**

**Date of examination (dd MMM yyyy)**

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Afifah Ayub (b) (4) | 20 Aug 2020 17:33:31 |
| User entered '3 Aug 2020'                              | Afifah Ayub (b) (4) | 04 Aug 2020 13:17:43 |

US3212013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:46:15

[Was study treatment given?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Nirja Shah (b) (4)<br>(b) (4) | 03 Aug 2020 21:21:20 |

US3212013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:46:15

If No, reason not given

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Nirja Shah (b) (4)<br>(b) (4) | 03 Aug 2020 21:21:20 |

US3212013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:46:15

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Nirja Shah (b) (4)<br>(b) (4) | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:46:15**

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 03 Aug 2020 21:21:20 |



US3212013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:46:15

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '03 Aug 2020' | Nirja Shah (b) (4)<br>(b) (4) | 03 Aug 2020 21:21:20 |

US3212013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:46:15

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                | User                          | Time (GMT)           |
|----------------------|-------------------------------|----------------------|
| User entered '16:19' | Nirja Shah (b) (4)<br>(b) (4) | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:46:15**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Aug 2020 16:19' | System | 03 Aug 2020 21:21:20 |

US3212013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:46:15

Which arm was used to give treatment?

| Audit                              | User                          | Time (GMT)           |
|------------------------------------|-------------------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Nirja Shah (b) (4)<br>(b) (4) | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:46:15**

[What was the frequency of the study treatment dosing?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:46:15**

[What was the route of administration for the study treatment?](#)

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 03 Aug 2020 21:21:20 |

US3212013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:15

[Was the sample collected?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:17:06 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:46:15**

**Collection date** (*dd MMM yyyy*)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| User entered '3 Aug 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:17:06 |



**US3212013**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:46:15**

**Collection time (00:00-23:59)**

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| User entered '15:37' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:17:06 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:46:15**

[Collection date and time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '3 Aug 2020 15:37' | System | 04 Aug 2020 13:17:06 |

US3212013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:46:15

Collection date (*dd MMM yyyy*)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| User entered '3 Aug 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:16:21 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Lab Test](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:16:21 |

US3212013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:46:15

[Was the sample collected?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:16:21 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:46:15**

**Collection time (00:00 - 23:59)**

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| User entered '15:30' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:16:21 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Collection date and time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '3 Aug 2020 15:30' | System | 04 Aug 2020 13:16:21 |

US3212013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:46:15

[Lab Test](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Afifah Ayub (b) (4)<br>(b) (4) | 04 Aug 2020 13:16:21 |



**US3212013**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Was the sample collected?](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | Laura Ngansop Djampou<br>(b) (4) | 25 Aug 2020 19:51:54 |
| User entered 'Yes (Y)'                                    | Afifah Ayub (b) (4)<br>(b) (4)   | 04 Aug 2020 13:16:21 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Collection time \(00:00 - 23:59\)](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Laura Ngansop Djampou<br>(b) (4) | 25 Aug 2020 19:51:54 |
| User entered '15:30'                                   | Afifah Ayub (b) (4)<br>(b) (4)   | 04 Aug 2020 13:16:21 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Collection date and time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered empty.             | System | 25 Aug 2020 19:51:54 |
| User entered '3 Aug 2020 15:30' | System | 04 Aug 2020 13:16:21 |

US3212013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:46:15

[Is the participant continuing to the next visit?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Afifah Ayub (b) (4)<br>(b) (4) | 18 Aug 2020 19:22:49 |

**US3212013**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:46:15**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Aug 2020 19:22:49 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**Was TEMPERATURE taken?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:55:42', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2a369c85-fcea-4af4-8ac8-8df56806feb6' | System | 03 Aug 2020 21:56:02 |
| User entered 'Yes (Y)'   | System | 03 Aug 2020 21:56:02 |

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:46:15

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:55:47', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2a369c85-fcea-4af4-8ac8-8df56806feb6' | System | 03 Aug 2020 21:56:02 |
| User entered '97.1'  | System | 03 Aug 2020 21:56:02 |



US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:46:15

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:55:53', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2a369c85-fcea-4af4-8ac8-8df56806feb6' | System | 03 Aug 2020 21:56:02 |
| User entered 'No (N)'  | System | 03 Aug 2020 21:56:02 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:55:58', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2a369c85-fcea-4af4-8ac8-8df56806feb6' | System | 03 Aug 2020 21:56:02 |
| User entered '03 Aug 2020 16:55'   | System | 03 Aug 2020 21:56:02 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Aug 2020 16:39' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Aug 2020 19:09' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Data entry locked.                                | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 1, after vaccination (at home)' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**Was TEMPERATURE taken?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:40:37', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b5d1886b-0339-4c7e-991b-71aff567f4cc' | System | 04 Aug 2020 02:41:06 |
| User entered 'Yes (Y)'   | System | 04 Aug 2020 02:41:06 |

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:46:15

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:40:49', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b5d1886b-0339-4c7e-991b-71aff567f4cc' | System | 04 Aug 2020 02:41:06 |
| User entered '98.7'  | System | 04 Aug 2020 02:41:06 |

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:46:15

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:40:52', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b5d1886b-0339-4c7e-991b-71aff567f4cc' | System | 04 Aug 2020 02:41:06 |
| User entered 'No (N)'  | System | 04 Aug 2020 02:41:06 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:40:54', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b5d1886b-0339-4c7e-991b-71aff567f4cc' | System | 04 Aug 2020 02:41:06 |
| User entered '03 Aug 2020 21:40'   | System | 04 Aug 2020 02:41:06 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Aug 2020 20:04' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 2' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**Was TEMPERATURE taken?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T18:06:24', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1dca15b2-7fe2-4e23-85eb-0f4eb84dd0e0' | System | 04 Aug 2020 23:06:48 |
| User entered 'Yes (Y)'   | System | 04 Aug 2020 23:06:48 |

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:46:15

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T18:06:31', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1dca15b2-7fe2-4e23-85eb-0f4eb84dd0e0' | System | 04 Aug 2020 23:06:48 |
| User entered '98.1'  | System | 04 Aug 2020 23:06:48 |

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:46:15

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T18:06:34', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1dca15b2-7fe2-4e23-85eb-0f4eb84dd0e0' | System | 04 Aug 2020 23:06:48 |
| User entered 'No (N)'  | System | 04 Aug 2020 23:06:48 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T18:06:44', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1dca15b2-7fe2-4e23-85eb-0f4eb84dd0e0' | System | 04 Aug 2020 23:06:48 |
| User entered '04 Aug 2020 18:06'   | System | 04 Aug 2020 23:06:48 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Aug 2020 12:00' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 3' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**Was TEMPERATURE taken?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:38:49', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3e129890-8a99-4ee1-b409-1944c303ad67' | System | 05 Aug 2020 22:39:04 |
| User entered 'Yes (Y)'   | System | 05 Aug 2020 22:39:04 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:38:56', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3e129890-8a99-4ee1-b409-1944c303ad67' | System | 05 Aug 2020 22:39:04 |
| User entered '98.5'  | System | 05 Aug 2020 22:39:04 |

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:46:15

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:38:58', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3e129890-8a99-4ee1-b409-1944c303ad67' | System | 05 Aug 2020 22:39:04 |
| User entered 'No (N)'  | System | 05 Aug 2020 22:39:04 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:01', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3e129890-8a99-4ee1-b409-1944c303ad67' | System | 05 Aug 2020 22:39:04 |
| User entered '05 Aug 2020 17:39'   | System | 05 Aug 2020 22:39:04 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Aug 2020 12:00' | System | 03 Aug 2020 21:21:20 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 4' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**Was TEMPERATURE taken?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:53:33', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a7d27a98-bb6f-4c78-b3c8-6ec0c8e3c2e9' | System | 06 Aug 2020 19:54:29 |
| User entered 'Yes (Y)'   | System | 06 Aug 2020 19:54:29 |

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:46:15

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:54:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a7d27a98-bb6f-4c78-b3c8-6ec0c8e3c2e9' | System | 06 Aug 2020 19:54:29 |
| User entered '98.1'  | System | 06 Aug 2020 19:54:29 |

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:46:15

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:54:24', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a7d27a98-bb6f-4c78-b3c8-6ec0c8e3c2e9' | System | 06 Aug 2020 19:54:29 |
| User entered 'No (N)'  | System | 06 Aug 2020 19:54:29 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:54:26', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a7d27a98-bb6f-4c78-b3c8-6ec0c8e3c2e9' | System | 06 Aug 2020 19:54:29 |
| User entered '06 Aug 2020 14:54'   | System | 06 Aug 2020 19:54:29 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Aug 2020 12:00' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 5' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**Was TEMPERATURE taken?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:08:39', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2256f277-331f-42ee-9d86-5f0945ea7db6' | System | 07 Aug 2020 23:08:55 |
| User entered 'Yes (Y)'   | System | 07 Aug 2020 23:08:55 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:08:42', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2256f277-331f-42ee-9d86-5f0945ea7db6' | System | 07 Aug 2020 23:08:55 |
| User entered '99.2'  | System | 07 Aug 2020 23:08:55 |

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:46:15

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:08:45', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2256f277-331f-42ee-9d86-5f0945ea7db6' | System | 07 Aug 2020 23:08:55 |
| User entered 'No (N)'  | System | 07 Aug 2020 23:08:55 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:08:52', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2256f277-331f-42ee-9d86-5f0945ea7db6' | System | 07 Aug 2020 23:08:55 |
| User entered '07 Aug 2020 18:08'   | System | 07 Aug 2020 23:08:55 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 12:00' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 6' | System | 03 Aug 2020 21:21:20 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**Was TEMPERATURE taken?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:05:42', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3378c207-e543-47df-8472-3f38738062fc' | System | 08 Aug 2020 23:06:01 |
| User entered 'Yes (Y)'   | System | 08 Aug 2020 23:06:01 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

Please record your **TEMPERATURE in °F**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:05:46', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3378c207-e543-47df-8472-3f38738062fc' | System | 08 Aug 2020 23:06:01 |
| User entered '98.5'  | System | 08 Aug 2020 23:06:01 |

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:46:15

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:05:49', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3378c207-e543-47df-8472-3f38738062fc' | System | 08 Aug 2020 23:06:01 |
| User entered 'No (N)'  | System | 08 Aug 2020 23:06:01 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:05:54', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3378c207-e543-47df-8472-3f38738062fc' | System | 08 Aug 2020 23:06:01 |
| User entered '08 Aug 2020 18:05'   | System | 08 Aug 2020 23:06:01 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Aug 2020 12:00' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 7' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**Was TEMPERATURE taken?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:48:43', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '542d05fa-90e9-4462-9c8b-191e5805de1d' | System | 09 Aug 2020 17:48:56 |
| User entered 'Yes (Y)'   | System | 09 Aug 2020 17:48:56 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:48:46', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '542d05fa-90e9-4462-9c8b-191e5805de1d' | System | 09 Aug 2020 17:48:56 |
| User entered '98.1'  | System | 09 Aug 2020 17:48:56 |

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:46:15

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:48:48', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '542d05fa-90e9-4462-9c8b-191e5805de1d' | System | 09 Aug 2020 17:48:56 |
| User entered 'No (N)'  | System | 09 Aug 2020 17:48:56 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:48:53', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '542d05fa-90e9-4462-9c8b-191e5805de1d' | System | 09 Aug 2020 17:48:56 |
| User entered '09 Aug 2020 12:48'   | System | 09 Aug 2020 17:48:56 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Aug 2020 12:00' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:18', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cd0fa6cf-d9d3-4f95-a955-dada08283820' | System | 03 Aug 2020 21:56:36 |
| User entered 'None (1)'  | System | 03 Aug 2020 21:56:36 |

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:46:15

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:23', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cd0fa6cf-d9d3-4f95-a955-dada08283820' | System | 03 Aug 2020 21:56:36 |
| User entered 'No (N)'  | System | 03 Aug 2020 21:56:36 |



US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:46:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:26', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cd0fa6cf-d9d3-4f95-a955-dada08283820' | System | 03 Aug 2020 21:56:36 |
| User entered 'No (N)'  | System | 03 Aug 2020 21:56:36 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:29', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cd0fa6cf-d9d3-4f95-a955-dada08283820' | System | 03 Aug 2020 21:56:36 |
| User entered 'None (1)'  | System | 03 Aug 2020 21:56:36 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:31', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cd0fa6cf-d9d3-4f95-a955-dada08283820' | System | 03 Aug 2020 21:56:36 |
| User entered '03 Aug 2020 16:56'   | System | 03 Aug 2020 21:56:36 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Aug 2020 16:39' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Aug 2020 19:09' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Data entry locked.                                | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 1, after vaccination (at home)' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '883bf0ac-84f1-4c88-9ab1-e82e89d02658' | System | 04 Aug 2020 02:41:20 |
| User entered 'None (1)'  | System | 04 Aug 2020 02:41:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

Is there any **REDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:07', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '883bf0ac-84f1-4c88-9ab1-e82e89d02658' | System | 04 Aug 2020 02:41:20 |
| User entered 'No (N)'  | System | 04 Aug 2020 02:41:20 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:11', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '883bf0ac-84f1-4c88-9ab1-e82e89d02658' | System | 04 Aug 2020 02:41:20 |
| User entered 'No (N)'  | System | 04 Aug 2020 02:41:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:14', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '883bf0ac-84f1-4c88-9ab1-e82e89d02658' | System | 04 Aug 2020 02:41:20 |
| User entered 'None (1)'  | System | 04 Aug 2020 02:41:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:15', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '883bf0ac-84f1-4c88-9ab1-e82e89d02658' | System | 04 Aug 2020 02:41:20 |
| User entered '03 Aug 2020 21:41'   | System | 04 Aug 2020 02:41:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Aug 2020 20:04' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 2' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:26:30', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '158a24ee-2c13-47f6-ba81-a70507ea8326' | System | 04 Aug 2020 21:27:14 |
| User entered 'None (1)'  | System | 04 Aug 2020 21:27:14 |

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:46:15

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:26:34', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '158a24ee-2c13-47f6-ba81-a70507ea8326' | System | 04 Aug 2020 21:27:14 |
| User entered 'No (N)'  | System | 04 Aug 2020 21:27:14 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:26:40', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '158a24ee-2c13-47f6-ba81-a70507ea8326' | System | 04 Aug 2020 21:27:14 |
| User entered 'Yes (Y)'   | System | 04 Aug 2020 21:27:14 |

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:46:15

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:27:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '158a24ee-2c13-47f6-ba81-a70507ea8326' | System | 04 Aug 2020 21:27:14 |
| User entered '1'   | System | 04 Aug 2020 21:27:14 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:27:06', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '158a24ee-2c13-47f6-ba81-a70507ea8326' | System | 04 Aug 2020 21:27:14 |
| User entered 'None (1)'  | System | 04 Aug 2020 21:27:14 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:27:10', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '158a24ee-2c13-47f6-ba81-a70507ea8326' | System | 04 Aug 2020 21:27:14 |
| User entered '04 Aug 2020 16:27'   | System | 04 Aug 2020 21:27:14 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Aug 2020 12:00' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 3' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:06', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '328ea280-ac6f-4e9e-b087-9a22e7b77af9' | System | 05 Aug 2020 22:39:27 |
| User entered 'None (1)'  | System | 05 Aug 2020 22:39:27 |



US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:46:15

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:12', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '328ea280-ac6f-4e9e-b087-9a22e7b77af9' | System | 05 Aug 2020 22:39:27 |
| User entered 'No (N)'  | System | 05 Aug 2020 22:39:27 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:16', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '328ea280-ac6f-4e9e-b087-9a22e7b77af9' | System | 05 Aug 2020 22:39:27 |
| User entered 'No (N)'  | System | 05 Aug 2020 22:39:27 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:22', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '328ea280-ac6f-4e9e-b087-9a22e7b77af9' | System | 05 Aug 2020 22:39:27 |
| User entered 'None (1)'  | System | 05 Aug 2020 22:39:27 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:24', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '328ea280-ac6f-4e9e-b087-9a22e7b77af9' | System | 05 Aug 2020 22:39:27 |
| User entered '05 Aug 2020 17:39'   | System | 05 Aug 2020 22:39:27 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Aug 2020 12:00' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 4' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:49:39', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '0da16527-71a8-4051-93b8-fd0756684044' | System | 06 Aug 2020 19:49:57 |
| User entered 'None (1)'  | System | 06 Aug 2020 19:49:57 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

Is there any **REDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:49:42', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '0da16527-71a8-4051-93b8-fd0756684044' | System | 06 Aug 2020 19:49:57 |
| User entered 'No (N)'  | System | 06 Aug 2020 19:49:57 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:49:44', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '0da16527-71a8-4051-93b8-fd0756684044' | System | 06 Aug 2020 19:49:57 |
| User entered 'No (N)'  | System | 06 Aug 2020 19:49:57 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:49:49', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '0da16527-71a8-4051-93b8-fd0756684044' | System | 06 Aug 2020 19:49:57 |
| User entered 'None (1)'  | System | 06 Aug 2020 19:49:57 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:49:54', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '0da16527-71a8-4051-93b8-fd0756684044' | System | 06 Aug 2020 19:49:57 |
| User entered '06 Aug 2020 14:49'   | System | 06 Aug 2020 19:49:57 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Aug 2020 12:00' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 5' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:08:55', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '308ab892-3ec6-4fe8-9643-6e10055ea722' | System | 07 Aug 2020 23:09:16 |
| User entered 'None (1)'  | System | 07 Aug 2020 23:09:16 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

Is there any **REDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:08:57', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '308ab892-3ec6-4fe8-9643-6e10055ea722' | System | 07 Aug 2020 23:09:16 |
| User entered 'No (N)'  | System | 07 Aug 2020 23:09:16 |

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:46:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:06', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '308ab892-3ec6-4fe8-9643-6e10055ea722' | System | 07 Aug 2020 23:09:16 |
| User entered 'No (N)'  | System | 07 Aug 2020 23:09:16 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:08', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '308ab892-3ec6-4fe8-9643-6e10055ea722' | System | 07 Aug 2020 23:09:16 |
| User entered 'None (1)'  | System | 07 Aug 2020 23:09:16 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:10', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '308ab892-3ec6-4fe8-9643-6e10055ea722' | System | 07 Aug 2020 23:09:16 |
| User entered '07 Aug 2020 18:09'   | System | 07 Aug 2020 23:09:16 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 12:00' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 6' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:05:57', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '4010050e-1aa6-4979-81e9-eaada7296a64' | System | 08 Aug 2020 23:06:17 |
| User entered 'None (1)'  | System | 08 Aug 2020 23:06:17 |



US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:46:15

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '4010050e-1aa6-4979-81e9-eaada7296a64' | System | 08 Aug 2020 23:06:17 |
| User entered 'No (N)'  | System | 08 Aug 2020 23:06:17 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:02', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '4010050e-1aa6-4979-81e9-eaada7296a64' | System | 08 Aug 2020 23:06:17 |
| User entered 'No (N)'  | System | 08 Aug 2020 23:06:17 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:04', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '4010050e-1aa6-4979-81e9-eaada7296a64' | System | 08 Aug 2020 23:06:17 |
| User entered 'None (1)'  | System | 08 Aug 2020 23:06:17 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:11', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '4010050e-1aa6-4979-81e9-eaada7296a64' | System | 08 Aug 2020 23:06:17 |
| User entered '08 Aug 2020 18:06'   | System | 08 Aug 2020 23:06:17 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Aug 2020 12:00' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 7' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '980c9b03-913a-4c66-a009-4d753d39cbc9' | System | 09 Aug 2020 17:49:14 |
| User entered 'None (1)'  | System | 09 Aug 2020 17:49:14 |



US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:46:15

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:02', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '980c9b03-913a-4c66-a009-4d753d39cbc9' | System | 09 Aug 2020 17:49:14 |
| User entered 'No (N)'  | System | 09 Aug 2020 17:49:14 |

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:46:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:04', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '980c9b03-913a-4c66-a009-4d753d39cbc9' | System | 09 Aug 2020 17:49:14 |
| User entered 'No (N)'  | System | 09 Aug 2020 17:49:14 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:08', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '980c9b03-913a-4c66-a009-4d753d39cbc9' | System | 09 Aug 2020 17:49:14 |
| User entered 'None (1)'  | System | 09 Aug 2020 17:49:14 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:10', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '980c9b03-913a-4c66-a009-4d753d39cbc9' | System | 09 Aug 2020 17:49:14 |
| User entered '09 Aug 2020 12:49'   | System | 09 Aug 2020 17:49:14 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Aug 2020 12:00' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:40', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a5ae45cb-942e-4a12-b5d3-8571390a4eb4' | System | 03 Aug 2020 21:56:56 |
| User entered 'None (0)'  | System | 03 Aug 2020 21:56:56 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:42', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a5ae45cb-942e-4a12-b5d3-8571390a4eb4' | System | 03 Aug 2020 21:56:56 |
| User entered 'None (0)'  | System | 03 Aug 2020 21:56:56 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:43', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a5ae45cb-942e-4a12-b5d3-8571390a4eb4' | System | 03 Aug 2020 21:56:56 |
| User entered 'None (0)'  | System | 03 Aug 2020 21:56:56 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:45', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a5ae45cb-942e-4a12-b5d3-8571390a4eb4' | System | 03 Aug 2020 21:56:56 |
| User entered 'None (0)'  | System | 03 Aug 2020 21:56:56 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:46', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a5ae45cb-942e-4a12-b5d3-8571390a4eb4' | System | 03 Aug 2020 21:56:56 |
| User entered 'None (0)'  | System | 03 Aug 2020 21:56:56 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:48', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a5ae45cb-942e-4a12-b5d3-8571390a4eb4' | System | 03 Aug 2020 21:56:56 |
| User entered 'None (0)'  | System | 03 Aug 2020 21:56:56 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:50', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a5ae45cb-942e-4a12-b5d3-8571390a4eb4' | System | 03 Aug 2020 21:56:56 |
| User entered 'No (N)'  | System | 03 Aug 2020 21:56:56 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:52', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a5ae45cb-942e-4a12-b5d3-8571390a4eb4' | System | 03 Aug 2020 21:56:56 |
| User entered '03 Aug 2020 16:56'   | System | 03 Aug 2020 21:56:56 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Aug 2020 16:39' | System | 03 Aug 2020 21:21:20 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Aug 2020 19:09' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Data entry locked.                                | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 1, after vaccination (at home)' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f2e099b-6b61-44c6-9970-5db06fd1bb5b' | System | 04 Aug 2020 02:41:40 |
| User entered 'None (0)'  | System | 04 Aug 2020 02:41:40 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:21', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f2e099b-6b61-44c6-9970-5db06fd1bb5b' | System | 04 Aug 2020 02:41:40 |
| User entered 'None (0)'  | System | 04 Aug 2020 02:41:40 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:22', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f2e099b-6b61-44c6-9970-5db06fd1bb5b' | System | 04 Aug 2020 02:41:40 |
| User entered 'None (0)'  | System | 04 Aug 2020 02:41:40 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:23', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f2e099b-6b61-44c6-9970-5db06fd1bb5b' | System | 04 Aug 2020 02:41:40 |
| User entered 'None (0)'  | System | 04 Aug 2020 02:41:40 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:25', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f2e099b-6b61-44c6-9970-5db06fd1bb5b' | System | 04 Aug 2020 02:41:40 |
| User entered 'None (0)'  | System | 04 Aug 2020 02:41:40 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:27', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f2e099b-6b61-44c6-9970-5db06fd1bb5b' | System | 04 Aug 2020 02:41:40 |
| User entered 'None (0)'  | System | 04 Aug 2020 02:41:40 |



US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:46:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:31', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f2e099b-6b61-44c6-9970-5db06fd1bb5b' | System | 04 Aug 2020 02:41:40 |
| User entered 'No (N)'  | System | 04 Aug 2020 02:41:40 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:37', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f2e099b-6b61-44c6-9970-5db06fd1bb5b' | System | 04 Aug 2020 02:41:40 |
| User entered '03 Aug 2020 21:41'   | System | 04 Aug 2020 02:41:40 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Aug 2020 20:04' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 2' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:27:19', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f82e9e77-3b99-4cfe-9126-009c47244986' | System | 04 Aug 2020 21:28:24 |
| User entered 'None (0)'  | System | 04 Aug 2020 21:28:24 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:27:26', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f82e9e77-3b99-4cfe-9126-009c47244986' | System | 04 Aug 2020 21:28:24 |
| User entered 'Some interference with activity (2)'   | System | 04 Aug 2020 21:28:24 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:27:37', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f82e9e77-3b99-4cfe-9126-009c47244986' | System | 04 Aug 2020 21:28:24 |
| User entered 'Some interference with activity (2)'   | System | 04 Aug 2020 21:28:24 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:27:41', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f82e9e77-3b99-4cfe-9126-009c47244986' | System | 04 Aug 2020 21:28:24 |
| User entered 'None (0)'  | System | 04 Aug 2020 21:28:24 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:27:57', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f82e9e77-3b99-4cfe-9126-009c47244986' | System | 04 Aug 2020 21:28:24 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'  | System | 04 Aug 2020 21:28:24 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:28:01', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f82e9e77-3b99-4cfe-9126-009c47244986' | System | 04 Aug 2020 21:28:24 |
| User entered 'None (0)'  | System | 04 Aug 2020 21:28:24 |

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:46:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:28:06', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f82e9e77-3b99-4cfe-9126-009c47244986' | System | 04 Aug 2020 21:28:24 |
| User entered 'No (N)'  | System | 04 Aug 2020 21:28:24 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:28:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f82e9e77-3b99-4cfe-9126-009c47244986' | System | 04 Aug 2020 21:28:24 |
| User entered '04 Aug 2020 16:28'   | System | 04 Aug 2020 21:28:24 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Aug 2020 12:00' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 3' | System | 03 Aug 2020 21:21:20 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:28', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c6897fd3-4b5a-4253-b647-7cae5722dfd8' | System | 05 Aug 2020 22:39:58 |
| User entered 'None (0)'  | System | 05 Aug 2020 22:39:58 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:33', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c6897fd3-4b5a-4253-b647-7cae5722dfd8' | System | 05 Aug 2020 22:39:58 |
| User entered 'None (0)'  | System | 05 Aug 2020 22:39:58 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:35', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c6897fd3-4b5a-4253-b647-7cae5722dfd8' | System | 05 Aug 2020 22:39:58 |
| User entered 'None (0)'  | System | 05 Aug 2020 22:39:58 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:38', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c6897fd3-4b5a-4253-b647-7cae5722dfd8' | System | 05 Aug 2020 22:39:58 |
| User entered 'None (0)'  | System | 05 Aug 2020 22:39:58 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:40', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c6897fd3-4b5a-4253-b647-7cae5722dfd8' | System | 05 Aug 2020 22:39:58 |
| User entered 'None (0)'  | System | 05 Aug 2020 22:39:58 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:41', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c6897fd3-4b5a-4253-b647-7cae5722dfd8' | System | 05 Aug 2020 22:39:58 |
| User entered 'None (0)'  | System | 05 Aug 2020 22:39:58 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:45', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c6897fd3-4b5a-4253-b647-7cae5722dfd8' | System | 05 Aug 2020 22:39:58 |
| User entered 'No (N)'  | System | 05 Aug 2020 22:39:58 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:53', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c6897fd3-4b5a-4253-b647-7cae5722dfd8' | System | 05 Aug 2020 22:39:58 |
| User entered '05 Aug 2020 17:39'   | System | 05 Aug 2020 22:39:58 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Aug 2020 12:00' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 4' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:50:03', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '8e66ce12-becb-4e7b-8083-98dc03711edc' | System | 06 Aug 2020 19:50:48 |
| User entered 'None (0)'  | System | 06 Aug 2020 19:50:48 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:50:33', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '8e66ce12-becb-4e7b-8083-98dc03711edc' | System | 06 Aug 2020 19:50:48 |
| User entered 'None (0)'  | System | 06 Aug 2020 19:50:48 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:50:35', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '8e66ce12-becb-4e7b-8083-98dc03711edc' | System | 06 Aug 2020 19:50:48 |
| User entered 'None (0)'  | System | 06 Aug 2020 19:50:48 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:50:37', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '8e66ce12-becb-4e7b-8083-98dc03711edc' | System | 06 Aug 2020 19:50:48 |
| User entered 'None (0)'  | System | 06 Aug 2020 19:50:48 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:50:38', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '8e66ce12-becb-4e7b-8083-98dc03711edc' | System | 06 Aug 2020 19:50:48 |
| User entered 'None (0)'  | System | 06 Aug 2020 19:50:48 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:50:40', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '8e66ce12-becb-4e7b-8083-98dc03711edc' | System | 06 Aug 2020 19:50:48 |
| User entered 'None (0)'  | System | 06 Aug 2020 19:50:48 |

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:46:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:50:43', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '8e66ce12-becb-4e7b-8083-98dc03711edc' | System | 06 Aug 2020 19:50:48 |
| User entered 'No (N)'  | System | 06 Aug 2020 19:50:48 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:50:45', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '8e66ce12-becb-4e7b-8083-98dc03711edc' | System | 06 Aug 2020 19:50:48 |
| User entered '06 Aug 2020 14:50'   | System | 06 Aug 2020 19:50:48 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Aug 2020 12:00' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 5' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:14', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5c1eb005-393d-4c3a-8418-4ca9931357be' | System | 07 Aug 2020 23:09:34 |
| User entered 'None (0)'  | System | 07 Aug 2020 23:09:34 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:16', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5c1eb005-393d-4c3a-8418-4ca9931357be' | System | 07 Aug 2020 23:09:34 |
| User entered 'None (0)'  | System | 07 Aug 2020 23:09:34 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:17', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5c1eb005-393d-4c3a-8418-4ca9931357be' | System | 07 Aug 2020 23:09:34 |
| User entered 'None (0)'  | System | 07 Aug 2020 23:09:34 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5c1eb005-393d-4c3a-8418-4ca9931357be' | System | 07 Aug 2020 23:09:34 |
| User entered 'None (0)'  | System | 07 Aug 2020 23:09:34 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:24', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5c1eb005-393d-4c3a-8418-4ca9931357be' | System | 07 Aug 2020 23:09:34 |
| User entered 'None (0)'  | System | 07 Aug 2020 23:09:34 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:27', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5c1eb005-393d-4c3a-8418-4ca9931357be' | System | 07 Aug 2020 23:09:34 |
| User entered 'None (0)'  | System | 07 Aug 2020 23:09:34 |

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:46:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:29', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5c1eb005-393d-4c3a-8418-4ca9931357be' | System | 07 Aug 2020 23:09:34 |
| User entered 'No (N)'  | System | 07 Aug 2020 23:09:34 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:31', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5c1eb005-393d-4c3a-8418-4ca9931357be' | System | 07 Aug 2020 23:09:34 |
| User entered '07 Aug 2020 18:09'   | System | 07 Aug 2020 23:09:34 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 12:00' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 6' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:15', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3cfbfada-0cb0-4057-8b48-66ba228a3486' | System | 08 Aug 2020 23:06:32 |
| User entered 'None (0)'  | System | 08 Aug 2020 23:06:32 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:16', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3cfbfada-0cb0-4057-8b48-66ba228a3486' | System | 08 Aug 2020 23:06:32 |
| User entered 'None (0)'  | System | 08 Aug 2020 23:06:32 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:18', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3cfbfada-0cb0-4057-8b48-66ba228a3486' | System | 08 Aug 2020 23:06:32 |
| User entered 'None (0)'  | System | 08 Aug 2020 23:06:32 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3cfbfada-0cb0-4057-8b48-66ba228a3486' | System | 08 Aug 2020 23:06:32 |
| User entered 'None (0)'  | System | 08 Aug 2020 23:06:32 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:21', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3cfbfada-0cb0-4057-8b48-66ba228a3486' | System | 08 Aug 2020 23:06:32 |
| User entered 'None (0)'  | System | 08 Aug 2020 23:06:32 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:23', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3cfbfada-0cb0-4057-8b48-66ba228a3486' | System | 08 Aug 2020 23:06:32 |
| User entered 'None (0)'  | System | 08 Aug 2020 23:06:32 |

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:46:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:25', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3cfbfada-0cb0-4057-8b48-66ba228a3486' | System | 08 Aug 2020 23:06:32 |
| User entered 'No (N)'  | System | 08 Aug 2020 23:06:32 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:26', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3cfbfada-0cb0-4057-8b48-66ba228a3486' | System | 08 Aug 2020 23:06:32 |
| User entered '08 Aug 2020 18:06'   | System | 08 Aug 2020 23:06:32 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Aug 2020 12:00' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 7' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:14', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '83bd688a-206a-47ca-b033-5af1f315f1e1' | System | 09 Aug 2020 17:49:31 |
| User entered 'None (0)'  | System | 09 Aug 2020 17:49:31 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:15', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '83bd688a-206a-47ca-b033-5af1f315f1e1' | System | 09 Aug 2020 17:49:31 |
| User entered 'None (0)'  | System | 09 Aug 2020 17:49:31 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:17', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '83bd688a-206a-47ca-b033-5af1f315f1e1' | System | 09 Aug 2020 17:49:31 |
| User entered 'None (0)'  | System | 09 Aug 2020 17:49:31 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:18', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '83bd688a-206a-47ca-b033-5af1f315f1e1' | System | 09 Aug 2020 17:49:31 |
| User entered 'None (0)'  | System | 09 Aug 2020 17:49:31 |



**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:19', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '83bd688a-206a-47ca-b033-5af1f315f1e1' | System | 09 Aug 2020 17:49:31 |
| User entered 'None (0)'  | System | 09 Aug 2020 17:49:31 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:21', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '83bd688a-206a-47ca-b033-5af1f315f1e1' | System | 09 Aug 2020 17:49:31 |
| User entered 'None (0)'  | System | 09 Aug 2020 17:49:31 |

US3212013

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:46:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:23', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '83bd688a-206a-47ca-b033-5af1f315f1e1' | System | 09 Aug 2020 17:49:31 |
| User entered 'No (N)'  | System | 09 Aug 2020 17:49:31 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:28', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '83bd688a-206a-47ca-b033-5af1f315f1e1' | System | 09 Aug 2020 17:49:31 |
| User entered '09 Aug 2020 12:49'   | System | 09 Aug 2020 17:49:31 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Aug 2020 12:00' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Aug 2020 11:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

[Was Contact Attempted?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Heather Leary (b) (4)<br>(b) (4) | 18 Aug 2020 20:12:09 |

**US3212013**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '10 Aug 2020' | Heather Leary (b) (4)<br>(b) (4) | 18 Aug 2020 20:12:09 |



**US3212013**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Heather Leary (b) (4)<br>(b) (4) | 18 Aug 2020 20:12:09 |

**US3212013**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Heather Leary (b) (4)<br>(b) (4) | 18 Aug 2020 20:12:09 |

US3212013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:15

[Is the participant continuing to the next visit?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Heather Leary (b) (4)<br>(b) (4) | 18 Aug 2020 20:12:12 |

**US3212013**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:46:15**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 18 Aug 2020 20:12:12 |

**US3212013**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

[Was Contact Attempted?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Heather Leary (b) (4)<br>(b) (4) | 18 Aug 2020 20:12:21 |

US3212013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '17 Aug 2020' | Heather Leary (b) (4)<br>(b) (4) | 18 Aug 2020 20:12:21 |

**US3212013**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Heather Leary (b) (4)<br>(b) (4) | 18 Aug 2020 20:12:21 |

**US3212013**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Heather Leary (b) (4)<br>(b) (4) | 18 Aug 2020 20:12:21 |



US3212013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:15

[Is the participant continuing to the next visit?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Laura Ngansop Djampou<br>(b) (4) | 25 Aug 2020 14:22:44 |

**US3212013**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:46:15**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 25 Aug 2020 14:22:44 |

**US3212013**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

[Was Contact Attempted?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Laura Ngansop Djampou<br>(b) (4) | 25 Aug 2020 14:22:57 |

**US3212013**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '24 Aug 2020' | Laura Ngansop Djampou<br>(b) (4) | 25 Aug 2020 14:22:57 |

**US3212013**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Laura Ngansop Djampou<br>(b) (4) | 25 Aug 2020 14:22:57 |

**US3212013**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Laura Ngansop Djampou<br>(b) (4) | 25 Aug 2020 14:22:57 |

**US3212013**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:46:15**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Laura Ngansop Djampou<br>(b) (4) | 25 Aug 2020 14:23:05 |

**US3212013**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:46:15**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 25 Aug 2020 14:23:05 |



US3212013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:15

[Was this visit performed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Afifah Ayub (b) (4)<br>(b) (4) | 02 Sep 2020 17:13:23 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:15

Visit date (dd MMM yyyy)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).                            | (b) (4), (b) (6)               | 11 Nov 2020 16:03:45 |
| Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'illness visit occurred' (Site from System). | Afifah Ayub (b) (4)<br>(b) (4) | 07 Oct 2020 20:53:42 |
| User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).                            | System                         | 07 Oct 2020 20:53:27 |
| User entered '7 Oct 2020' reason for change: Data Entry Error   | Afifah Ayub (b) (4)<br>(b) (4) | 07 Oct 2020 20:53:27 |
| User entered '31 Aug 2020' reason for change: Data Entry Error  | Afifah Ayub (b) (4)<br>(b) (4) | 02 Sep 2020 17:14:40 |
| User entered '2 Sep 2020'   | Afifah Ayub (b) (4)<br>(b) (4) | 02 Sep 2020 17:13:23 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:15

Was visit performed at the participant's home or at the clinic?

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Afifah Ayub (b) (4)<br>(b) (4) | 02 Sep 2020 17:13:23 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:46:15**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 02 Sep 2020 17:13:23 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

[Timepoint](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Laura Ngansop Djampou<br>(b) (4) | 09 Sep 2020 14:37:17 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

Were vital signs assessed?

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Laura Ngansop Djampou<br>(b) (4) | 09 Sep 2020 14:37:17 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

Date of assessment (*dd MMM yyyy*)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System                        | 07 Oct 2020 20:57:01 |
| User entered '7 Oct 2020' reason for change: Data Entry Error  | Afifah Ayub (b) (4)           | 07 Oct 2020 20:57:01 |
| User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System                        | 07 Oct 2020 20:53:27 |
| User entered '31 Aug 2020'   | Laura Ngansop Djampou (b) (4) | 09 Sep 2020 14:37:17 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

Time of assessment (00:00-23:59)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| User entered '14:58' reason for change: Data Entry Error | Afifah Ayub (b) (4)           | 07 Oct 2020 20:57:01 |
| User entered '16:13'                                     | Laura Ngansop Djampou (b) (4) | 09 Sep 2020 14:37:17 |



**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '7 Oct 2020 14:58'  | System | 07 Oct 2020 20:57:01 |
| User entered '31 Aug 2020 16:13' | System | 09 Sep 2020 14:37:17 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

Temperature (xxx.x)

| Audit   | User                          | Time (GMT)           |
|---|-------------------------------|----------------------|
| User entered '97.5' F reason for change: Data Entry Error | Afifah Ayub (b) (4)           | 07 Oct 2020 20:57:01 |
| User entered '98.4' F                                     | Laura Ngansop Djampou (b) (4) | 09 Sep 2020 14:37:17 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

[Route of measurement](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered 'Oral (Oral)' | Laura Ngansop Djampou<br>(b) (4) | 09 Sep 2020 14:37:17 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:46:15**

[If Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Laura Ngansop Djampou<br>(b) (4) | 09 Sep 2020 14:37:17 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

[Pulse \(xxx\)](#)

| Audit   | User                          | Time (GMT)           |
|---|-------------------------------|----------------------|
| User entered '88' reason for change: Data Entry Error | Afifah Ayub (b) (4)           | 07 Oct 2020 20:57:01 |
| User entered '83'                                     | Laura Ngansop Djampou (b) (4) | 09 Sep 2020 14:37:17 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 09 Sep 2020 14:37:17 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

[Respiratory Rate \(xxx\)](#)

| Audit   | User                          | Time (GMT)           |
|---|-------------------------------|----------------------|
| User entered '14' reason for change: Data Entry Error | Afifah Ayub (b) (4)           | 07 Oct 2020 20:57:01 |
| User entered '17'                                     | Laura Ngansop Djampou (b) (4) | 09 Sep 2020 14:37:17 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 09 Sep 2020 14:37:17 |



US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

Systolic Blood Pressure (xxx)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| User entered '124' reason for change: Data Entry Error | Afifah Ayub (b) (4)           | 07 Oct 2020 20:57:01 |
| User entered '135'                                     | Laura Ngansop Djampou (b) (4) | 09 Sep 2020 14:37:17 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 09 Sep 2020 14:37:17 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:46:15

Diastolic Blood Pressure (xxx)

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '88' | Laura Ngansop Djampou<br>(b) (4) | 09 Sep 2020 14:37:17 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 09 Sep 2020 14:37:17 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

[Timepoint](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Afifah Ayub (b) (4)<br>(b) (4) | 07 Oct 2020 20:57:01 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

[Were vital signs assessed?](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 13 Oct 2020 20:03:10 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 13 Oct 2020 20:03:10 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | Anna Pena (b) (4)   | 13 Oct 2020 20:03:10 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 07 Oct 2020 20:57:47 |
| User entered empty; reason for change Data Entry Error                                 | Afifah Ayub (b) (4) | 07 Oct 2020 20:57:47 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 07 Oct 2020 20:57:20 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 07 Oct 2020 20:57:20 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Afifah Ayub (b) (4) | 07 Oct 2020 20:57:20 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 07 Oct 2020 20:57:01 |
| User entered empty.  | Afifah Ayub (b) (4) | 07 Oct 2020 20:57:01 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

Date of assessment (*dd MMM yyyy*)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User entered '07 Oct 2020' reason for change: Data Entry Error | Anna Pena (b) (4)   | 13 Oct 2020 20:03:10 |
| User entered empty.  | (b) (4)             |                      |
|  | Afifah Ayub (b) (4) | 07 Oct 2020 20:57:01 |
|  | (b) (4)             |                      |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:46:15**

**Time of assessment (00:00-23:59)**

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User entered '16:28' reason for change: Data Entry Error | Anna Pena (b) (4)   | 13 Oct 2020 20:03:10 |
| User entered empty.                                      | Afifah Ayub (b) (4) | 07 Oct 2020 20:57:01 |



**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 16:28' | System | 13 Oct 2020 20:03:10 |
| User entered empty.              | System | 07 Oct 2020 20:57:01 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

Temperature (xxx.x)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User closed query 'Data is required. Please provide.'<br>(Site from System).                    | System                         | 13 Oct 2020 20:04:13 |
| Query 'Data is required. Please provide.' answered by System<br>data change (Site from System). |                                | 13 Oct 2020 20:04:13 |
| User entered '98.2' F reason for change: Data Entry<br>Error                                    | Anna Pena (b) (4)<br>(b) (4)   | 13 Oct 2020 20:04:13 |
| User opened query 'Data is required. Please provide.'<br>(Site from System).                    | System                         | 13 Oct 2020 20:03:10 |
| User entered empty.   | Afifah Ayub (b) (4)<br>(b) (4) | 07 Oct 2020 20:57:01 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

[Route of measurement](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).                    | System                         | 13 Oct 2020 20:04:22 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                                | 13 Oct 2020 20:04:22 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error                               | Anna Pena (b) (4)<br>(b) (4)   | 13 Oct 2020 20:04:22 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                         | 13 Oct 2020 20:04:13 |
| User entered empty.  | Afifah Ayub (b) (4)<br>(b) (4) | 07 Oct 2020 20:57:01 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:46:15**

[If Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 07 Oct 2020 20:57:01 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

[Pulse \(xxx\)](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).                    | System                         | 13 Oct 2020 20:04:13 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                                | 13 Oct 2020 20:04:13 |
| User entered '75' reason for change: Data Entry Error  | Anna Pena (b) (4)<br>(b) (4)   | 13 Oct 2020 20:04:13 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                         | 13 Oct 2020 20:03:10 |
| User entered empty.  | Afifah Ayub (b) (4)<br>(b) (4) | 07 Oct 2020 20:57:01 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'bpm'  | System | 13 Oct 2020 20:04:13 |
| User entered empty. | System | 07 Oct 2020 20:57:01 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

[Respiratory Rate \(xxx\)](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).                    | System                         | 13 Oct 2020 20:04:13 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                                | 13 Oct 2020 20:04:13 |
| User entered '16' reason for change: Data Entry Error  | Anna Pena (b) (4)<br>(b) (4)   | 13 Oct 2020 20:04:13 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                         | 13 Oct 2020 20:03:10 |
| User entered empty.  | Afifah Ayub (b) (4)<br>(b) (4) | 07 Oct 2020 20:57:01 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 13 Oct 2020 20:04:13 |
| User entered empty.        | System | 07 Oct 2020 20:57:01 |



US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

[Systolic Blood Pressure \(xxx\)](#)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User closed query 'Data is required. Please provide.'<br>(Site from System).                    | System                         | 13 Oct 2020 20:04:13 |
| Query 'Data is required. Please provide.' answered by System<br>data change (Site from System). |                                | 13 Oct 2020 20:04:13 |
| User entered '132' reason for change: Data Entry<br>Error                                       | Anna Pena (b) (4)<br>(b) (4)   | 13 Oct 2020 20:04:13 |
| User opened query 'Data is required. Please provide.'<br>(Site from System).                    | System                         | 13 Oct 2020 20:03:10 |
| User entered empty.   | Afifah Ayub (b) (4)<br>(b) (4) | 07 Oct 2020 20:57:01 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 13 Oct 2020 20:04:13 |
| User entered empty. | System | 07 Oct 2020 20:57:01 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

[Diastolic Blood Pressure \(xxx\)](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).                    | System                         | 13 Oct 2020 20:04:13 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                                | 13 Oct 2020 20:04:13 |
| User entered '88' reason for change: Data Entry Error  | Anna Pena (b) (4)<br>(b) (4)   | 13 Oct 2020 20:04:13 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                         | 13 Oct 2020 20:03:10 |
| User entered empty.  | Afifah Ayub (b) (4)<br>(b) (4) | 07 Oct 2020 20:57:01 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:46:15

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 13 Oct 2020 20:04:13 |
| User entered empty. | System | 07 Oct 2020 20:57:01 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:15

Was the physical examination performed?

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Afifah Ayub (b) (4)<br>(b) (4) | 02 Sep 2020 17:14:00 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:15

Date of examination (dd MMM yyyy)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System              | 07 Oct 2020 20:54:11 |
| User entered '7 Oct 2020' reason for change: Data Entry Error  | Afifah Ayub (b) (4) | 07 Oct 2020 20:54:11 |
| User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System              | 07 Oct 2020 20:53:27 |
| User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System              | 02 Sep 2020 17:14:40 |
| User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System              | 02 Sep 2020 17:14:27 |
| User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System              | 02 Sep 2020 17:14:27 |
| User entered '31 Aug 2020' reason for change: Data Entry Error   | Afifah Ayub (b) (4) | 02 Sep 2020 17:14:27 |
| User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System              | 02 Sep 2020 17:14:00 |
| User entered '1 Sep 2020'  | Afifah Ayub (b) (4) | 02 Sep 2020 17:14:00 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:46:15

[Was study treatment given?](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User entered 'Yes (Y)' reason for change: New Information | Heather Leary (b) (4)<br>(b) (4) | 07 Oct 2020 20:50:29 |
| User entered 'No (N)'                                     | Afifah Ayub (b) (4)<br>(b) (4)   | 02 Sep 2020 17:15:12 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:46:15**

[If No, reason not given](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| User entered empty; reason for change New Information  | Heather Leary (b) (4) | 07 Oct 2020 20:50:29 |
| User entered 'Protocol Deviation (PROTOCOL DEVIATION)' | Afifah Ayub (b) (4)   | 02 Sep 2020 17:15:12 |



US3212013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:46:15

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| User entered empty; reason for change Data Entry Error                         | Heather Leary (b) (4) | 07 Oct 2020 20:50:29 |
| User entered 'Subject received blood transfusions -prohibited as per protocol' | Afifah Ayub (b) (4)   | 02 Sep 2020 17:15:12 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:46:15**

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 07 Oct 2020 20:50:29 |
| User entered empty.                 | System | 02 Sep 2020 17:15:12 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:46:15

What was the treatment date? (dd MMM yyyy)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User closed query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify''. (Site from DM).                                  | (b) (4), (b) (6)                 | 18 Nov 2020 15:17:45 |
| Query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify''. answered with 'AEs updated for dose delayed' (Site from DM). | Heather Leary (b) (4)<br>(b) (4) | 20 Oct 2020 21:12:44 |
| User opened query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify''. (Site from DM).                                  | (b) (4), (b) (6)                 | 19 Oct 2020 18:39:39 |
| User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).   | (b) (4), (b) (6)                 | 13 Oct 2020 09:35:04 |
| Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered with 'Dose was delayed due to blood transfusion, PI approved dosage for this date' (Site from System).                                   | Heather Leary (b) (4)<br>(b) (4) | 07 Oct 2020 20:50:47 |
| User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).   | System                           | 07 Oct 2020 20:50:29 |
| User entered '7 Oct 2020' reason for change: New Information  | Heather Leary (b) (4)<br>(b) (4) | 07 Oct 2020 20:50:29 |
| User entered empty.   | Afifah Ayub (b) (4)<br>(b) (4)   | 02 Sep 2020 17:15:12 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:46:15

[What was the treatment time? \(00:00-23:59\)](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User entered '15:43' reason for change: New Information | Heather Leary (b) (4) | 07 Oct 2020 20:50:29 |
| User entered empty.                                     | (b) (4)               |                      |
|   | Afifah Ayub (b) (4)   | 02 Sep 2020 17:15:12 |
|   | (b) (4)               |                      |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:46:15**

[Treatment Date and Time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '7 Oct 2020 15:43' | System | 07 Oct 2020 20:50:29 |
| User entered empty.             | System | 02 Sep 2020 17:15:12 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:46:15

[Which arm was used to give treatment?](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' reason for change: New Information | Heather Leary (b) (4) | 07 Oct 2020 20:50:29 |
| User entered empty.   | (b) (4)               |                      |
|   | Afifah Ayub (b) (4)   | 02 Sep 2020 17:15:12 |
|   | (b) (4)               |                      |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:46:15

[What was the frequency of the study treatment dosing?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 07 Oct 2020 20:50:29 |
| User entered empty. | System | 02 Sep 2020 17:15:12 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:46:15**

[What was the route of administration for the study treatment?](#)

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 07 Oct 2020 20:50:29 |
| User entered empty.          | System | 02 Sep 2020 17:15:12 |



US3212013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:15

[Was the sample collected?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Afifah Ayub (b) (4)<br>(b) (4) | 02 Sep 2020 17:15:31 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:15

Collection date (dd MMM yyyy)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Query 'Per GCL Lab Reconciliation:<br>Immunogenicity: Sample dated 07OCT2020<br>collected for Visit 2 Day 29 visit in EDC is reported<br>under Unscheduled [1] visit in PPD Central lab.<br>Please reconcile the correct Visit and update if<br>applicable. Else clarify, thank you.' answered with '<br>Sample dated 07OCT2020 collected for Visit 2 Day<br>29 visit. Query resolved in PPD Preclarus Portal'<br>(Site from DM). | (b) (4), (b) (6)                 | 16 Nov 2020 22:12:41 |
| User entered '07 Oct 2020' reason for change: Data<br>Entry Error   | Heather Leary (b) (4)<br>(b) (4) | 11 Nov 2020 21:45:13 |
| User opened query 'Per GCL Lab Reconciliation:<br>Immunogenicity: Sample dated 07OCT2020<br>collected for Visit 2 Day 29 visit in EDC is reported<br>under Unscheduled [1] visit in PPD Central lab.<br>Please reconcile the correct Visit and update if<br>applicable. Else clarify, thank you.' (Site from DM).   | (b) (4), (b) (6)                 | 11 Nov 2020 09:42:26 |
| User closed query 'Per GCL Lab Reconciliation:<br>Antibody-mediated Immunogenicity: Sample dated<br>07OCT2020 is recorded under Visit2 Day29 in EDC,<br>however the same is reported under Visit2 Day29<br>with date 31AUG2020 in PPD Central lab. Please<br>review and confirm the correct date and update as<br>appropriate, else clarify.' (Site from DM).   | (b) (4), (b) (6)                 | 29 Oct 2020 16:42:05 |
| Query 'Per GCL Lab Reconciliation:<br>Antibody-mediated Immunogenicity: Sample dated<br>07OCT2020 is recorded under Visit2 Day29 in EDC,<br>however the same is reported under Visit2 Day29<br>with date 31AUG2020 in PPD Central lab. Please<br>review and confirm the correct date and update as<br>appropriate, else clarify.' answered with 'The data<br>entered is correct.' (Site from DM).                                 | Afifah Ayub (b) (4)<br>(b) (4)   | 28 Oct 2020 21:17:49 |
| User opened query 'Per GCL Lab Reconciliation:<br>Antibody-mediated Immunogenicity: Sample dated<br>07OCT2020 is recorded under Visit2 Day29 in EDC,<br>however the same is reported under Visit2 Day29<br>with date 31AUG2020 in PPD Central lab. Please<br>review and confirm the correct date and update as<br>appropriate, else clarify.' (Site from DM).   | (b) (4), (b) (6)                 | 23 Oct 2020 11:03:46 |
| User closed query 'The Collection Date is not equal<br>to Visit Date. Please review and reconcile.' (Site from<br>System).  | System                           | 07 Oct 2020 20:55:04 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:15

Collection date (*dd MMM yyyy*)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System). |                     | 07 Oct 2020 20:55:04 |
| User entered '7 Oct 2020' reason for change: Data Entry Error   | Afifah Ayub (b) (4) | 07 Oct 2020 20:55:04 |
| User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).                    | System              | 07 Oct 2020 20:53:27 |
| User entered '31 Aug 2020'  | Afifah Ayub (b) (4) | 02 Sep 2020 17:15:31 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:15

Collection time (00:00-23:59)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User entered '15:25' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 07 Oct 2020 20:56:02 |
| User entered '15:20' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 07 Oct 2020 20:55:34 |
| User entered '15:25' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 07 Oct 2020 20:55:18 |
| User entered '16:40'                                     | Afifah Ayub (b) (4) | 02 Sep 2020 17:15:31 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:46:15**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 15:25' | System | 11 Nov 2020 21:45:13 |
| User entered '7 Oct 2020 15:25'  | System | 07 Oct 2020 20:56:02 |
| User entered '7 Oct 2020 15:20'  | System | 07 Oct 2020 20:55:34 |
| User entered '7 Oct 2020 15:25'  | System | 07 Oct 2020 20:55:18 |
| User entered '7 Oct 2020 16:40'  | System | 07 Oct 2020 20:55:04 |
| User entered '31 Aug 2020 16:40' | System | 02 Sep 2020 17:15:31 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:46:15

Collection date (dd MMM yyyy)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| Query 'Per GCL Lab Reconciliation: Swab: Sample dated 07OCT2020 is recorded under Visit 2 Day 29 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.<br>' answered with 'An unscheduled visit was done to collect NP swab. Please clarify your query.' (Site from DM). | Reagan Reed (b) (4)<br>(b) (4) | 06 Nov 2020 15:02:08 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 07OCT2020 is recorded under Visit 2 Day 29 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.<br>' (Site from DM).  | (b) (4), (b) (6)<br>(b) (4)    | 02 Nov 2020 04:51:45 |
| User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 07OCT2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under Visit2 Day29 Visit with date 31AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).                                   | (b) (4), (b) (6)<br>(b) (4)    | 29 Oct 2020 16:41:59 |
| Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 07OCT2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under Visit2 Day29 Visit with date 31AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'The data entered is correct.' (Site from DM).  | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 21:15:38 |
| User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 07OCT2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under Visit2 Day29 Visit with date 31AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).                                   | (b) (4), (b) (6)<br>(b) (4)    | 22 Oct 2020 16:46:10 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:46:15

Collection date (*dd MMM yyyy*)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).                    | System                         | 07 Oct 2020 20:55:53 |
| Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System). |                                | 07 Oct 2020 20:55:53 |
| User entered '7 Oct 2020' reason for change: Data Entry Error   | Afifah Ayub (b) (4)<br>(b) (4) | 07 Oct 2020 20:55:53 |
| User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).                    | System                         | 07 Oct 2020 20:53:27 |
| User entered '31 Aug 2020'  | Afifah Ayub (b) (4)<br>(b) (4) | 02 Sep 2020 17:15:48 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Lab Test](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Afifah Ayub (b) (4)<br>(b) (4) | 02 Sep 2020 17:15:48 |



US3212013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:46:15

[Was the sample collected?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Afifah Ayub (b) (4)<br>(b) (4) | 02 Sep 2020 17:15:48 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:46:15**

**Collection time (00:00 - 23:59)**

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User entered '15:20' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 07 Oct 2020 20:55:53 |
| User entered '16:35'                                     | Afifah Ayub (b) (4) | 02 Sep 2020 17:15:48 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '7 Oct 2020 15:20'  | System | 07 Oct 2020 20:55:53 |
| User entered '31 Aug 2020 16:35' | System | 02 Sep 2020 17:15:48 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:46:15

[Lab Test](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Afifah Ayub (b) (4)<br>(b) (4) | 02 Sep 2020 17:15:48 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:46:15

[Was the sample collected?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 02 Sep 2020 17:15:48 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:46:15**

**Collection time (00:00 - 23:59)**

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 02 Sep 2020 17:15:48 |

**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Collection date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Sep 2020 17:15:48 |

US3212013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:15

[Is the participant continuing to the next visit?](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User entered 'Yes (Y)' reason for change: Data Entry Error | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:13:28 |
| User entered 'No (N)'                                      | Afifah Ayub (b) (4)<br>(b) (4)   | 02 Sep 2020 17:16:03 |



**US3212013**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:46:15**

[Continuing Flag](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1'    | System | 14 Sep 2020 16:13:28 |
| User entered empty. | System | 02 Sep 2020 17:16:03 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 07 Oct 2020 20:50:29 |

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:46:15

Was **TEMPERATURE** taken?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:20:33', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a6e6855d-0c75-4778-927d-025f45983d4e' | System | 07 Oct 2020 21:20:47 |
| User entered 'Yes (Y)'   | System | 07 Oct 2020 21:20:47 |

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:46:15

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:20:38', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a6e6855d-0c75-4778-927d-025f45983d4e' | System | 07 Oct 2020 21:20:47 |
| User entered '98.2'  | System | 07 Oct 2020 21:20:47 |

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:46:15

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:20:40', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a6e6855d-0c75-4778-927d-025f45983d4e' | System | 07 Oct 2020 21:20:47 |
| User entered 'No (N)'  | System | 07 Oct 2020 21:20:47 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:20:43', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a6e6855d-0c75-4778-927d-025f45983d4e' | System | 07 Oct 2020 21:20:47 |
| User entered '07 Oct 2020 16:20'   | System | 07 Oct 2020 21:20:47 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 16:03' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 18:33' | System | 07 Oct 2020 20:50:29 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Data entry locked.                                | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 1, after vaccination (at home)' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**Was TEMPERATURE taken?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:19:33', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '4c394eb7-920a-4f31-9325-4e0b25bbb83a' | System | 08 Oct 2020 03:20:24 |
| User entered 'Yes (Y)'   | System | 08 Oct 2020 03:20:24 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:20:10', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '4c394eb7-920a-4f31-9325-4e0b25bbb83a' | System | 08 Oct 2020 03:20:24 |
| User entered '99.1'  | System | 08 Oct 2020 03:20:24 |

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:46:15

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:20:12', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '4c394eb7-920a-4f31-9325-4e0b25bbb83a' | System | 08 Oct 2020 03:20:24 |
| User entered 'No (N)'  | System | 08 Oct 2020 03:20:24 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:20:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '4c394eb7-920a-4f31-9325-4e0b25bbb83a' | System | 08 Oct 2020 03:20:24 |
| User entered '07 Oct 2020 22:20'   | System | 08 Oct 2020 03:20:24 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 19:28' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 2' | System | 07 Oct 2020 20:50:29 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**Was TEMPERATURE taken?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:55:24', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5551d8aa-1150-4708-83ce-7eea5df2651c' | System | 08 Oct 2020 18:56:45 |
| User entered 'Yes (Y)'   | System | 08 Oct 2020 18:56:45 |

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:46:15

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:56:35', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5551d8aa-1150-4708-83ce-7eea5df2651c' User entered '98.3' | System | 08 Oct 2020 18:56:45 |

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:46:15

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:56:38', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5551d8aa-1150-4708-83ce-7eea5df2651c' | System | 08 Oct 2020 18:56:45 |
| User entered 'No (N)'  | System | 08 Oct 2020 18:56:45 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:56:41', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5551d8aa-1150-4708-83ce-7eea5df2651c' | System | 08 Oct 2020 18:56:45 |
| User entered '08 Oct 2020 13:56'   | System | 08 Oct 2020 18:56:45 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Oct 2020 12:00' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 3' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**Was TEMPERATURE taken?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:24', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cf7f884a-b6c4-48fa-b598-efb05488928e' | System | 10 Oct 2020 03:21:42 |
| User entered 'Yes (Y)'   | System | 10 Oct 2020 03:21:42 |



US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:46:15

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:31', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cf7f884a-b6c4-48fa-b598-efb05488928e' | System | 10 Oct 2020 03:21:42 |
| User entered '98.9'  | System | 10 Oct 2020 03:21:42 |

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:46:15

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:34', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cf7f884a-b6c4-48fa-b598-efb05488928e' | System | 10 Oct 2020 03:21:42 |
| User entered 'No (N)'  | System | 10 Oct 2020 03:21:42 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:39', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cf7f884a-b6c4-48fa-b598-efb05488928e' | System | 10 Oct 2020 03:21:42 |
| User entered '09 Oct 2020 22:21'   | System | 10 Oct 2020 03:21:42 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Oct 2020 12:00' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 4' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**Was TEMPERATURE taken?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:48', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f0d82a2d-132e-4cd1-bb82-e6b07f30e7f7' | System | 10 Oct 2020 23:20:07 |
| User entered 'Yes (Y)'   | System | 10 Oct 2020 23:20:07 |

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:46:15

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:54', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f0d82a2d-132e-4cd1-bb82-e6b07f30e7f7' | System | 10 Oct 2020 23:20:07 |
| User entered '98.9'  | System | 10 Oct 2020 23:20:07 |



US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:46:15

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:58', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f0d82a2d-132e-4cd1-bb82-e6b07f30e7f7' | System | 10 Oct 2020 23:20:07 |
| User entered 'No (N)'  | System | 10 Oct 2020 23:20:07 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:20:01', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f0d82a2d-132e-4cd1-bb82-e6b07f30e7f7' | System | 10 Oct 2020 23:20:07 |
| User entered '10 Oct 2020 18:20'   | System | 10 Oct 2020 23:20:07 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Oct 2020 12:00' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 5' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**Was TEMPERATURE taken?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-11T23:59:48', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2632df7a-0bb3-458f-859c-7c58a0577ba9' | System | 12 Oct 2020 05:00:08 |
| User entered 'Yes (Y)'   | System | 12 Oct 2020 05:00:08 |

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:46:15

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-11T23:59:52', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2632df7a-0bb3-458f-859c-7c58a0577ba9' | System | 12 Oct 2020 05:00:08 |
| User entered '98.9'  | System | 12 Oct 2020 05:00:08 |

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:46:15

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-11T23:59:54', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2632df7a-0bb3-458f-859c-7c58a0577ba9' | System | 12 Oct 2020 05:00:08 |
| User entered 'No (N)'  | System | 12 Oct 2020 05:00:08 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:04', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2632df7a-0bb3-458f-859c-7c58a0577ba9' | System | 12 Oct 2020 05:00:08 |
| User entered '12 Oct 2020 00:00'   | System | 12 Oct 2020 05:00:08 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Oct 2020 12:00' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 6' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**Was TEMPERATURE taken?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:47:31', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1011891b-5841-4f10-bb62-ef55f6c15780' | System | 13 Oct 2020 05:47:48 |
| User entered 'Yes (Y)'   | System | 13 Oct 2020 05:47:48 |

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:46:15

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:47:38', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1011891b-5841-4f10-bb62-ef55f6c15780' | System | 13 Oct 2020 05:47:48 |
| User entered '99.0'  | System | 13 Oct 2020 05:47:48 |

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:46:15

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:47:40', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1011891b-5841-4f10-bb62-ef55f6c15780' | System | 13 Oct 2020 05:47:48 |
| User entered 'No (N)'  | System | 13 Oct 2020 05:47:48 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:47:46', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1011891b-5841-4f10-bb62-ef55f6c15780' | System | 13 Oct 2020 05:47:48 |
| User entered '13 Oct 2020 00:47'   | System | 13 Oct 2020 05:47:48 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Oct 2020 12:00' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 7' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**Was TEMPERATURE taken?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:27:02', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5cac6af6-8f47-4862-a300-172749f067f0' | System | 14 Oct 2020 03:28:22 |
| User entered 'Yes (Y)'   | System | 14 Oct 2020 03:28:22 |

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:46:15

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:15', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5cac6af6-8f47-4862-a300-172749f067f0' | System | 14 Oct 2020 03:28:22 |
| User entered '98.7'  | System | 14 Oct 2020 03:28:22 |

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:46:15

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:18', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5cac6af6-8f47-4862-a300-172749f067f0' | System | 14 Oct 2020 03:28:22 |
| User entered 'No (N)'  | System | 14 Oct 2020 03:28:22 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5cac6af6-8f47-4862-a300-172749f067f0' | System | 14 Oct 2020 03:28:22 |
| User entered '13 Oct 2020 22:28'   | System | 14 Oct 2020 03:28:22 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Oct 2020 12:00' | System | 07 Oct 2020 20:50:29 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:09', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b6241cab-cf32-40b2-ad8b-9b5e8603cf17' | System | 07 Oct 2020 21:21:22 |
| User entered 'None (1)'  | System | 07 Oct 2020 21:21:22 |

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:46:15

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:13', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b6241cab-cf32-40b2-ad8b-9b5e8603cf17' | System | 07 Oct 2020 21:21:22 |
| User entered 'No (N)'  | System | 07 Oct 2020 21:21:22 |

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:46:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:15', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b6241cab-cf32-40b2-ad8b-9b5e8603cf17' | System | 07 Oct 2020 21:21:22 |
| User entered 'No (N)'  | System | 07 Oct 2020 21:21:22 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:17', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b6241cab-cf32-40b2-ad8b-9b5e8603cf17' | System | 07 Oct 2020 21:21:22 |
| User entered 'None (1)'  | System | 07 Oct 2020 21:21:22 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b6241cab-cf32-40b2-ad8b-9b5e8603cf17' | System | 07 Oct 2020 21:21:22 |
| User entered '07 Oct 2020 16:21'   | System | 07 Oct 2020 21:21:22 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 16:03' | System | 07 Oct 2020 20:50:29 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 18:33' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Data entry locked.                                | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 1, after vaccination (at home)' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:20:51', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5093a860-4ef0-4fc9-a21a-3bff204409be' | System | 08 Oct 2020 03:21:26 |
| User entered 'Does not interfere with activity (2)'  | System | 08 Oct 2020 03:21:26 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

Is there any **REDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:21:05', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5093a860-4ef0-4fc9-a21a-3bff204409be' | System | 08 Oct 2020 03:21:26 |
| User entered 'No (N)'  | System | 08 Oct 2020 03:21:26 |

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:46:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:21:12', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5093a860-4ef0-4fc9-a21a-3bff204409be' | System | 08 Oct 2020 03:21:26 |
| User entered 'No (N)'  | System | 08 Oct 2020 03:21:26 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:21:18', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5093a860-4ef0-4fc9-a21a-3bff204409be' | System | 08 Oct 2020 03:21:26 |
| User entered 'None (1)'  | System | 08 Oct 2020 03:21:26 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:21:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5093a860-4ef0-4fc9-a21a-3bff204409be' | System | 08 Oct 2020 03:21:26 |
| User entered '07 Oct 2020 22:21'   | System | 08 Oct 2020 03:21:26 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 19:28' | System | 07 Oct 2020 20:50:29 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 2' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:56:55', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b13e3335-9d82-4ba7-878a-7759a63aa588' | System | 08 Oct 2020 18:57:26 |
| User entered 'Does not interfere with activity (2)'  | System | 08 Oct 2020 18:57:26 |

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:46:15

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:02', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b13e3335-9d82-4ba7-878a-7759a63aa588' | System | 08 Oct 2020 18:57:26 |
| User entered 'No (N)'  | System | 08 Oct 2020 18:57:26 |

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:46:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:08', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b13e3335-9d82-4ba7-878a-7759a63aa588' | System | 08 Oct 2020 18:57:26 |
| User entered 'No (N)'  | System | 08 Oct 2020 18:57:26 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:14', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b13e3335-9d82-4ba7-878a-7759a63aa588' | System | 08 Oct 2020 18:57:26 |
| User entered 'None (1)'  | System | 08 Oct 2020 18:57:26 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:19', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b13e3335-9d82-4ba7-878a-7759a63aa588' | System | 08 Oct 2020 18:57:26 |
| User entered '08 Oct 2020 13:57'   | System | 08 Oct 2020 18:57:26 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Oct 2020 12:00' | System | 07 Oct 2020 20:50:29 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 3' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:20:52', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '69ea5957-3f21-4cdd-abbf-5c61ba8b110d' | System | 10 Oct 2020 03:21:07 |
| User entered 'None (1)'  | System | 10 Oct 2020 03:21:07 |

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:46:15

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:20:54', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '69ea5957-3f21-4cdd-abbf-5c61ba8b110d' | System | 10 Oct 2020 03:21:07 |
| User entered 'No (N)'  | System | 10 Oct 2020 03:21:07 |

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:46:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:20:57', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '69ea5957-3f21-4cdd-abbf-5c61ba8b110d' | System | 10 Oct 2020 03:21:07 |
| User entered 'No (N)'  | System | 10 Oct 2020 03:21:07 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '69ea5957-3f21-4cdd-abbf-5c61ba8b110d' | System | 10 Oct 2020 03:21:07 |
| User entered 'None (1)'  | System | 10 Oct 2020 03:21:07 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:01', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '69ea5957-3f21-4cdd-abbf-5c61ba8b110d' | System | 10 Oct 2020 03:21:07 |
| User entered '09 Oct 2020 22:21'   | System | 10 Oct 2020 03:21:07 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Oct 2020 12:00' | System | 07 Oct 2020 20:50:29 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 4' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:12', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c5552a9c-b976-4974-b3a6-333fe7ca9324' | System | 10 Oct 2020 23:19:26 |
| User entered 'None (1)'  | System | 10 Oct 2020 23:19:26 |

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:46:15

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:15', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c5552a9c-b976-4974-b3a6-333fe7ca9324' | System | 10 Oct 2020 23:19:26 |
| User entered 'No (N)'  | System | 10 Oct 2020 23:19:26 |

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:46:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:19', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c5552a9c-b976-4974-b3a6-333fe7ca9324' | System | 10 Oct 2020 23:19:26 |
| User entered 'No (N)'  | System | 10 Oct 2020 23:19:26 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:22', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c5552a9c-b976-4974-b3a6-333fe7ca9324' | System | 10 Oct 2020 23:19:26 |
| User entered 'None (1)'  | System | 10 Oct 2020 23:19:26 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:25', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c5552a9c-b976-4974-b3a6-333fe7ca9324' | System | 10 Oct 2020 23:19:26 |
| User entered '10 Oct 2020 18:19'   | System | 10 Oct 2020 23:19:26 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Oct 2020 12:00' | System | 07 Oct 2020 20:50:29 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 5' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:08', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '91631990-62ae-431a-9bc8-a7aa7128be6b' | System | 12 Oct 2020 05:00:21 |
| User entered 'None (1)'  | System | 12 Oct 2020 05:00:21 |

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:46:15

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:11', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '91631990-62ae-431a-9bc8-a7aa7128be6b' | System | 12 Oct 2020 05:00:21 |
| User entered 'No (N)'  | System | 12 Oct 2020 05:00:21 |

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:46:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:13', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '91631990-62ae-431a-9bc8-a7aa7128be6b' | System | 12 Oct 2020 05:00:21 |
| User entered 'No (N)'  | System | 12 Oct 2020 05:00:21 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:15', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '91631990-62ae-431a-9bc8-a7aa7128be6b' | System | 12 Oct 2020 05:00:21 |
| User entered 'None (1)'  | System | 12 Oct 2020 05:00:21 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:17', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '91631990-62ae-431a-9bc8-a7aa7128be6b' | System | 12 Oct 2020 05:00:21 |
| User entered '12 Oct 2020 00:00'   | System | 12 Oct 2020 05:00:21 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Oct 2020 12:00' | System | 07 Oct 2020 20:50:29 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 6' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:47:56', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '64df016b-0cab-40b1-8d65-4a9c0a5b7427' | System | 13 Oct 2020 05:48:31 |
| User entered 'None (1)'  | System | 13 Oct 2020 05:48:31 |

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:46:15

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:47:58', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '64df016b-0cab-40b1-8d65-4a9c0a5b7427' | System | 13 Oct 2020 05:48:31 |
| User entered 'No (N)'  | System | 13 Oct 2020 05:48:31 |

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:46:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:01', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '64df016b-0cab-40b1-8d65-4a9c0a5b7427' | System | 13 Oct 2020 05:48:31 |
| User entered 'No (N)'  | System | 13 Oct 2020 05:48:31 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:02', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '64df016b-0cab-40b1-8d65-4a9c0a5b7427' | System | 13 Oct 2020 05:48:31 |
| User entered 'None (1)'  | System | 13 Oct 2020 05:48:31 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:26', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '64df016b-0cab-40b1-8d65-4a9c0a5b7427' | System | 13 Oct 2020 05:48:31 |
| User entered '13 Oct 2020 00:48'   | System | 13 Oct 2020 05:48:31 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Oct 2020 12:00' | System | 07 Oct 2020 20:50:29 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 7' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:23', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '51c07fec-033b-4021-853e-1f89c1d2baf3' | System | 14 Oct 2020 03:28:41 |
| User entered 'None (1)'  | System | 14 Oct 2020 03:28:41 |

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:46:15

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:25', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '51c07fec-033b-4021-853e-1f89c1d2baf3' | System | 14 Oct 2020 03:28:41 |
| User entered 'No (N)'  | System | 14 Oct 2020 03:28:41 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:27', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '51c07fec-033b-4021-853e-1f89c1d2baf3' | System | 14 Oct 2020 03:28:41 |
| User entered 'No (N)'  | System | 14 Oct 2020 03:28:41 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:28', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '51c07fec-033b-4021-853e-1f89c1d2baf3' | System | 14 Oct 2020 03:28:41 |
| User entered 'None (1)'  | System | 14 Oct 2020 03:28:41 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:35', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '51c07fec-033b-4021-853e-1f89c1d2baf3' | System | 14 Oct 2020 03:28:41 |
| User entered '13 Oct 2020 22:28'   | System | 14 Oct 2020 03:28:41 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Oct 2020 12:00' | System | 07 Oct 2020 20:50:29 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:23', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '24495028-1aa1-4f68-98ba-fa3dbb2393f1' | System | 07 Oct 2020 21:21:41 |
| User entered 'None (0)'  | System | 07 Oct 2020 21:21:41 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:25', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '24495028-1aa1-4f68-98ba-fa3dbb2393f1' | System | 07 Oct 2020 21:21:41 |
| User entered 'None (0)'  | System | 07 Oct 2020 21:21:41 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:26', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '24495028-1aa1-4f68-98ba-fa3dbb2393f1' | System | 07 Oct 2020 21:21:41 |
| User entered 'None (0)'  | System | 07 Oct 2020 21:21:41 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:28', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '24495028-1aa1-4f68-98ba-fa3dbb2393f1' User entered 'None (0)' | System | 07 Oct 2020 21:21:41 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:29', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '24495028-1aa1-4f68-98ba-fa3dbb2393f1' User entered 'None (0)' | System | 07 Oct 2020 21:21:41 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:30', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '24495028-1aa1-4f68-98ba-fa3dbb2393f1' | System | 07 Oct 2020 21:21:41 |
| User entered 'None (0)'  | System | 07 Oct 2020 21:21:41 |



US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:46:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:33', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '24495028-1aa1-4f68-98ba-fa3dbb2393f1' | System | 07 Oct 2020 21:21:41 |
| User entered 'No (N)'  | System | 07 Oct 2020 21:21:41 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time stamp](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:35', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '24495028-1aa1-4f68-98ba-fa3dbb2393f1' User entered '07 Oct 2020 16:21' | System | 07 Oct 2020 21:21:41 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 16:03' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 18:33' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Data entry locked.                                | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 1, after vaccination (at home)' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:21:26', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '168b8001-80d7-41b9-93c5-44d864b9d8c2' | System | 08 Oct 2020 03:22:09 |
| User entered 'None (0)'  | System | 08 Oct 2020 03:22:09 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:21:33', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '168b8001-80d7-41b9-93c5-44d864b9d8c2' | System | 08 Oct 2020 03:22:09 |
| User entered 'No interference with activity (1)'   | System | 08 Oct 2020 03:22:09 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:21:49', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '168b8001-80d7-41b9-93c5-44d864b9d8c2' | System | 08 Oct 2020 03:22:09 |
| User entered 'No interference with activity (1)'   | System | 08 Oct 2020 03:22:09 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:21:53', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '168b8001-80d7-41b9-93c5-44d864b9d8c2' | System | 08 Oct 2020 03:22:09 |
| User entered 'None (0)'  | System | 08 Oct 2020 03:22:09 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:21:59', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '168b8001-80d7-41b9-93c5-44d864b9d8c2' | System | 08 Oct 2020 03:22:09 |
| User entered 'None (0)'  | System | 08 Oct 2020 03:22:09 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:22:01', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '168b8001-80d7-41b9-93c5-44d864b9d8c2' | System | 08 Oct 2020 03:22:09 |
| User entered 'None (0)'  | System | 08 Oct 2020 03:22:09 |

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:46:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:22:04', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '168b8001-80d7-41b9-93c5-44d864b9d8c2' | System | 08 Oct 2020 03:22:09 |
| User entered 'No (N)'  | System | 08 Oct 2020 03:22:09 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:22:06', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '168b8001-80d7-41b9-93c5-44d864b9d8c2' | System | 08 Oct 2020 03:22:09 |
| User entered '07 Oct 2020 22:22'   | System | 08 Oct 2020 03:22:09 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 19:28' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 2' | System | 07 Oct 2020 20:50:29 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:27', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '78184763-6b06-4c13-b2a4-0ca6b297aea6' | System | 08 Oct 2020 18:57:48 |
| User entered 'None (0)'  | System | 08 Oct 2020 18:57:48 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:30', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '78184763-6b06-4c13-b2a4-0ca6b297aea6' | System | 08 Oct 2020 18:57:48 |
| User entered 'None (0)'  | System | 08 Oct 2020 18:57:48 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:35', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '78184763-6b06-4c13-b2a4-0ca6b297aea6' | System | 08 Oct 2020 18:57:48 |
| User entered 'None (0)'  | System | 08 Oct 2020 18:57:48 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:38', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '78184763-6b06-4c13-b2a4-0ca6b297aea6' | System | 08 Oct 2020 18:57:48 |
| User entered 'None (0)'  | System | 08 Oct 2020 18:57:48 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:40', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '78184763-6b06-4c13-b2a4-0ca6b297aea6' | System | 08 Oct 2020 18:57:48 |
| User entered 'None (0)'  | System | 08 Oct 2020 18:57:48 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:41', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '78184763-6b06-4c13-b2a4-0ca6b297aea6' | System | 08 Oct 2020 18:57:48 |
| User entered 'None (0)'  | System | 08 Oct 2020 18:57:48 |

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:46:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:44', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '78184763-6b06-4c13-b2a4-0ca6b297aea6' | System | 08 Oct 2020 18:57:48 |
| User entered 'No (N)'  | System | 08 Oct 2020 18:57:48 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:46', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '78184763-6b06-4c13-b2a4-0ca6b297aea6' | System | 08 Oct 2020 18:57:48 |
| User entered '08 Oct 2020 13:57'   | System | 08 Oct 2020 18:57:48 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Oct 2020 12:00' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 3' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:05', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5703e3a0-d870-4234-9e70-9269d12e8572' | System | 10 Oct 2020 03:21:20 |
| User entered 'None (0)'  | System | 10 Oct 2020 03:21:20 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:07', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5703e3a0-d870-4234-9e70-9269d12e8572' | System | 10 Oct 2020 03:21:20 |
| User entered 'None (0)'  | System | 10 Oct 2020 03:21:20 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:09', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5703e3a0-d870-4234-9e70-9269d12e8572' | System | 10 Oct 2020 03:21:20 |
| User entered 'None (0)'  | System | 10 Oct 2020 03:21:20 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:10', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5703e3a0-d870-4234-9e70-9269d12e8572' | System | 10 Oct 2020 03:21:20 |
| User entered 'None (0)'  | System | 10 Oct 2020 03:21:20 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:12', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5703e3a0-d870-4234-9e70-9269d12e8572' | System | 10 Oct 2020 03:21:20 |
| User entered 'None (0)'  | System | 10 Oct 2020 03:21:20 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:13', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5703e3a0-d870-4234-9e70-9269d12e8572' | System | 10 Oct 2020 03:21:20 |
| User entered 'None (0)'  | System | 10 Oct 2020 03:21:20 |

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:46:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:15', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5703e3a0-d870-4234-9e70-9269d12e8572' | System | 10 Oct 2020 03:21:20 |
| User entered 'No (N)'  | System | 10 Oct 2020 03:21:20 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:17', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5703e3a0-d870-4234-9e70-9269d12e8572' | System | 10 Oct 2020 03:21:20 |
| User entered '09 Oct 2020 22:21'   | System | 10 Oct 2020 03:21:20 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Oct 2020 12:00' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 4' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:28', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c8310d9f-6166-472b-92b3-a864ee3bfe76' | System | 10 Oct 2020 23:19:43 |
| User entered 'None (0)'  | System | 10 Oct 2020 23:19:43 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:30', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c8310d9f-6166-472b-92b3-a864ee3bfe76' | System | 10 Oct 2020 23:19:43 |
| User entered 'None (0)'  | System | 10 Oct 2020 23:19:43 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:31', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c8310d9f-6166-472b-92b3-a864ee3bfe76' | System | 10 Oct 2020 23:19:43 |
| User entered 'None (0)'  | System | 10 Oct 2020 23:19:43 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:34', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c8310d9f-6166-472b-92b3-a864ee3bfe76' | System | 10 Oct 2020 23:19:43 |
| User entered 'None (0)'  | System | 10 Oct 2020 23:19:43 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:35', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c8310d9f-6166-472b-92b3-a864ee3bfe76' | System | 10 Oct 2020 23:19:43 |
| User entered 'None (0)'  | System | 10 Oct 2020 23:19:43 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:37', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c8310d9f-6166-472b-92b3-a864ee3bfe76' | System | 10 Oct 2020 23:19:43 |
| User entered 'None (0)'  | System | 10 Oct 2020 23:19:43 |

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:46:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:38', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c8310d9f-6166-472b-92b3-a864ee3bfe76' | System | 10 Oct 2020 23:19:43 |
| User entered 'No (N)'  | System | 10 Oct 2020 23:19:43 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:41', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c8310d9f-6166-472b-92b3-a864ee3bfe76' | System | 10 Oct 2020 23:19:43 |
| User entered '10 Oct 2020 18:19'   | System | 10 Oct 2020 23:19:43 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Oct 2020 12:00' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 5' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:23', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '9f73ad54-87e1-4166-9bca-ba125506dda2' | System | 12 Oct 2020 05:00:37 |
| User entered 'None (0)'  | System | 12 Oct 2020 05:00:37 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:24', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '9f73ad54-87e1-4166-9bca-ba125506dda2' | System | 12 Oct 2020 05:00:37 |
| User entered 'None (0)'  | System | 12 Oct 2020 05:00:37 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:26', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '9f73ad54-87e1-4166-9bca-ba125506dda2' | System | 12 Oct 2020 05:00:37 |
| User entered 'None (0)'  | System | 12 Oct 2020 05:00:37 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:27', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '9f73ad54-87e1-4166-9bca-ba125506dda2' | System | 12 Oct 2020 05:00:37 |
| User entered 'None (0)'  | System | 12 Oct 2020 05:00:37 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:28', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '9f73ad54-87e1-4166-9bca-ba125506dda2' | System | 12 Oct 2020 05:00:37 |
| User entered 'None (0)'  | System | 12 Oct 2020 05:00:37 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:30', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '9f73ad54-87e1-4166-9bca-ba125506dda2' | System | 12 Oct 2020 05:00:37 |
| User entered 'None (0)'  | System | 12 Oct 2020 05:00:37 |

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:46:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:31', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '9f73ad54-87e1-4166-9bca-ba125506dda2' | System | 12 Oct 2020 05:00:37 |
| User entered 'No (N)'  | System | 12 Oct 2020 05:00:37 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:34', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '9f73ad54-87e1-4166-9bca-ba125506dda2' | System | 12 Oct 2020 05:00:37 |
| User entered '12 Oct 2020 00:00'   | System | 12 Oct 2020 05:00:37 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Oct 2020 12:00' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 6' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:30', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fb776db6-e295-401d-8cfd-56ef4b0f90ce' | System | 13 Oct 2020 05:48:42 |
| User entered 'None (0)'  | System | 13 Oct 2020 05:48:42 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:31', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fb776db6-e295-401d-8cfd-56ef4b0f90ce' | System | 13 Oct 2020 05:48:42 |
| User entered 'None (0)'  | System | 13 Oct 2020 05:48:42 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:32', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fb776db6-e295-401d-8cfd-56ef4b0f90ce' | System | 13 Oct 2020 05:48:42 |
| User entered 'None (0)'  | System | 13 Oct 2020 05:48:42 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:34', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fb776db6-e295-401d-8cfd-56ef4b0f90ce' | System | 13 Oct 2020 05:48:42 |
| User entered 'None (0)'  | System | 13 Oct 2020 05:48:42 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:35', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fb776db6-e295-401d-8cfd-56ef4b0f90ce' | System | 13 Oct 2020 05:48:42 |
| User entered 'None (0)'  | System | 13 Oct 2020 05:48:42 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:36', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fb776db6-e295-401d-8cfd-56ef4b0f90ce' | System | 13 Oct 2020 05:48:42 |
| User entered 'None (0)'  | System | 13 Oct 2020 05:48:42 |

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:46:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:38', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fb776db6-e295-401d-8cfd-56ef4b0f90ce' | System | 13 Oct 2020 05:48:42 |
| User entered 'No (N)'  | System | 13 Oct 2020 05:48:42 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:40', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fb776db6-e295-401d-8cfd-56ef4b0f90ce' | System | 13 Oct 2020 05:48:42 |
| User entered '13 Oct 2020 00:48'   | System | 13 Oct 2020 05:48:42 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Oct 2020 12:00' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Oct 2020 20:50:29 |
| User entered 'Day 7' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:41', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'dfdb8021-d82e-4485-a0ee-31f99a2dac2e' | System | 14 Oct 2020 03:28:59 |
| User entered 'None (0)'  | System | 14 Oct 2020 03:28:59 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:43', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'dfdb8021-d82e-4485-a0ee-31f99a2dac2e' | System | 14 Oct 2020 03:28:59 |
| User entered 'None (0)'  | System | 14 Oct 2020 03:28:59 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:44', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'dfdb8021-d82e-4485-a0ee-31f99a2dac2e' | System | 14 Oct 2020 03:28:59 |
| User entered 'None (0)'  | System | 14 Oct 2020 03:28:59 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:45', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'dfdb8021-d82e-4485-a0ee-31f99a2dac2e' | System | 14 Oct 2020 03:28:59 |
| User entered 'None (0)'  | System | 14 Oct 2020 03:28:59 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:47', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'dfdb8021-d82e-4485-a0ee-31f99a2dac2e' | System | 14 Oct 2020 03:28:59 |
| User entered 'None (0)'  | System | 14 Oct 2020 03:28:59 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:48', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'dfdb8021-d82e-4485-a0ee-31f99a2dac2e' | System | 14 Oct 2020 03:28:59 |
| User entered 'None (0)'  | System | 14 Oct 2020 03:28:59 |

US3212013

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:46:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:50', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'dfdb8021-d82e-4485-a0ee-31f99a2dac2e' | System | 14 Oct 2020 03:28:59 |
| User entered 'No (N)'  | System | 14 Oct 2020 03:28:59 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:56', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'dfdb8021-d82e-4485-a0ee-31f99a2dac2e' | System | 14 Oct 2020 03:28:59 |
| User entered '13 Oct 2020 22:28'   | System | 14 Oct 2020 03:28:59 |

**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Oct 2020 12:00' | System | 07 Oct 2020 20:50:29 |



**US3212013**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:46:15**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Oct 2020 11:59' | System | 07 Oct 2020 20:50:29 |

**US3212013**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

[Was Contact Attempted?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:23:25 |

US3212013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:15

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit   | User                          | Time (GMT)           |
|---|-------------------------------|----------------------|
| User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).   | (b) (4), (b) (6)              | 19 Oct 2020 16:08:28 |
| User entered '15 Oct 2020' reason for change: Data Entry Error  | Afifah Ayub (b) (4)           | 16 Oct 2020 20:27:54 |
| Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'dose was delayed due to subject receiving blood transfusion; safety calls after dosing will be captured as unscheduled visits' (Site from System). | Heather Leary (b) (4)         | 07 Oct 2020 21:47:31 |
| User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).   | System                        | 07 Oct 2020 20:50:29 |
| User entered '8 Sep 2020'   | Laura Ngansop Djampou (b) (4) | 14 Sep 2020 16:23:25 |

**US3212013**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:23:25 |

**US3212013**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:23:25 |

US3212013

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:15

[Is the participant continuing to the next visit?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:23:37 |

**US3212013**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:46:15**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 14 Sep 2020 16:23:37 |

**US3212013**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

[Was Contact Attempted?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Laura Ngansop Djampou<br>(b) (4) | 16 Sep 2020 13:41:56 |



US3212013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:15

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| User entered '21 Oct 2020' reason for change: Data Entry Error   | Afifah Ayub (b) (4)           | 22 Oct 2020 17:10:19 |
| User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).   | (b) (4), (b) (6)              | 19 Oct 2020 16:08:35 |
| Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'IP was withheld at V2 due to blood transfusion; PI permitted IP administration at later date (7Oct2020)' (Site from System). | Heather Leary (b) (4)         | 08 Oct 2020 16:28:23 |
| User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).   | System                        | 07 Oct 2020 20:50:29 |
| User entered '15 Sep 2020'   | Laura Ngansop Djampou (b) (4) | 16 Sep 2020 13:41:56 |

**US3212013**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Laura Ngansop Djampou<br>(b) (4) | 16 Sep 2020 13:41:56 |

**US3212013**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Laura Ngansop Djampou<br>(b) (4) | 16 Sep 2020 13:41:56 |

**US3212013**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:46:15**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Laura Ngansop Djampou<br>(b) (4) | 16 Sep 2020 13:42:02 |

**US3212013**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:46:15**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 16 Sep 2020 13:42:02 |

**US3212013**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

[Was Contact Attempted?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Laura Ngansop Djampou<br>(b) (4) | 01 Oct 2020 20:17:40 |

US3212013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:46:15

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit   | User                          | Time (GMT)           |
|---|-------------------------------|----------------------|
| User entered '28 Oct 2020' reason for change: Data Entry Error  | Afifah Ayub (b) (4)           | 28 Oct 2020 20:32:44 |
| User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).  | (b) (4), (b) (6)              | 19 Oct 2020 16:08:38 |
| Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'IP was not administered at initial V2 due to subject receiving blood transfusion; PI authorized administration of IP on 7Oct2020' (Site from System). | Heather Leary (b) (4)         | 08 Oct 2020 16:29:59 |
| User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).  | System                        | 07 Oct 2020 20:50:29 |
| User entered '21 Sep 2020'  | Laura Ngansop Djampou (b) (4) | 01 Oct 2020 20:17:40 |

**US3212013**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Laura Ngansop Djampou<br>(b) (4) | 01 Oct 2020 20:17:40 |



**US3212013**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:46:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Laura Ngansop Djampou<br>(b) (4) | 01 Oct 2020 20:17:40 |

US3212013

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:15

[Is the participant continuing to the next visit?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Laura Ngansop Djampou<br>(b) (4) | 01 Oct 2020 20:17:46 |

**US3212013**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:46:15**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 01 Oct 2020 20:17:46 |

**US3212013**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:46:15**

[Was this visit performed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:35:04 |

US3212013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:46:15

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User entered '4 Nov 2020' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:35:04 |

**US3212013**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:46:15**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:35:04 |

**US3212013**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:46:15**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT3' | System | 04 Nov 2020 21:35:04 |

**US3212013**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Were vital signs assessed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:36:01 |



US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User entered '4 Nov 2020' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:36:01 |

**US3212013**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

**Time of assessment (00:00-23:59)**

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| User entered '14:24' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:36:01 |

**US3212013**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '4 Nov 2020 14:24' | System | 04 Nov 2020 21:36:01 |

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

Temperature (xxx.x)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered '97.2' F | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:36:01 |

**US3212013**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Route of measurement](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered 'Oral (Oral)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:36:01 |

**US3212013**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[If Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:36:01 |

**US3212013**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Pulse \(xxx\)](#)

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '80' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:36:01 |

**US3212013**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 04 Nov 2020 21:36:01 |



US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

[Respiratory Rate \(xxx\)](#)

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '18' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:36:01 |

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 04 Nov 2020 21:36:01 |

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

Systolic Blood Pressure (xxx)

| Audit              | User                             | Time (GMT)           |
|--------------------|----------------------------------|----------------------|
| User entered '102' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:36:01 |

**US3212013**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 04 Nov 2020 21:36:01 |

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

Diastolic Blood Pressure (xxx)

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '79' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:36:01 |

**US3212013**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 04 Nov 2020 21:36:01 |

**US3212013**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:46:15**

[Was the physical examination performed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:35:14 |

US3212013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:15

Date of examination (*dd MMM yyyy*)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User entered '4 Nov 2020' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:35:14 |



US3212013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:15

[Was the sample collected?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:35:28 |

US3212013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:46:15

Collection date (*dd MMM yyyy*)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User entered '4 Nov 2020' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:35:28 |

**US3212013**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:46:15**

[Collection time \(00:00-23:59\)](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| User entered '15:21' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:35:28 |

**US3212013**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:46:15**

[Collection date and time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '4 Nov 2020 15:21' | System | 04 Nov 2020 21:35:28 |

US3212013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:46:15

[Is the participant continuing to the next visit?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:35:34 |

**US3212013**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:46:15**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 04 Nov 2020 21:35:34 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 64' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T14:31:45', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '27f33a8c-76eb-4660-84cd-2a7fe4d431db' | System | 07 Oct 2020 19:32:06 |
| User entered 'Yes (Y)'   | System | 07 Oct 2020 19:32:06 |



**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T14:31:48', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '27f33a8c-76eb-4660-84cd-2a7fe4d431db' | System | 07 Oct 2020 19:32:06 |
| User entered 'No (N)'  | System | 07 Oct 2020 19:32:06 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T14:31:51', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '27f33a8c-76eb-4660-84cd-2a7fe4d431db' | System | 07 Oct 2020 19:32:06 |
| User entered 'No (N)'  | System | 07 Oct 2020 19:32:06 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T14:31:56', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '27f33a8c-76eb-4660-84cd-2a7fe4d431db' | System | 07 Oct 2020 19:32:06 |
| User entered 'No (N)'  | System | 07 Oct 2020 19:32:06 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T14:31:59', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '27f33a8c-76eb-4660-84cd-2a7fe4d431db' | System | 07 Oct 2020 19:32:06 |
| User entered '07 Oct 2020 14:31:59'  | System | 07 Oct 2020 19:32:06 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 03 Aug 2020 21:21:20 |
| User entered '03 Oct 2020 00:01' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 03 Aug 2020 21:21:20 |
| User entered '07 Oct 2020 23:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 71' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T00:20:37', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '0cbd153a-f2c7-4095-9159-8794c55a4be3' | System | 10 Oct 2020 05:20:52 |
| User entered 'No (N)'  | System | 10 Oct 2020 05:20:52 |



**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T00:20:39', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '0cbd153a-f2c7-4095-9159-8794c55a4be3' | System | 10 Oct 2020 05:20:52 |
| User entered 'No (N)'  | System | 10 Oct 2020 05:20:52 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T00:20:48', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '0cbd153a-f2c7-4095-9159-8794c55a4be3' User entered '10 Oct 2020 00:20:48' | System | 10 Oct 2020 05:20:52 |
|  | System | 10 Oct 2020 05:20:52 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 03 Aug 2020 21:21:20 |
| User entered '10 Oct 2020 00:01' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 03 Aug 2020 21:21:20 |
| User entered '14 Oct 2020 23:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 78' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-21T02:40:44', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cbd5ec10-9c5d-4d0a-9c43-f7129406bf12' | System | 21 Oct 2020 07:40:57 |
| User entered 'No (N)'  | System | 21 Oct 2020 07:40:57 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-21T02:40:49', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cbd5ec10-9c5d-4d0a-9c43-f7129406bf12' | System | 21 Oct 2020 07:40:57 |
| User entered 'No (N)'  | System | 21 Oct 2020 07:40:57 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-21T02:40:54', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cbd5ec10-9c5d-4d0a-9c43-f7129406bf12' | System | 21 Oct 2020 07:40:57 |
| User entered '21 Oct 2020 02:40:54'  | System | 21 Oct 2020 07:40:57 |



**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 03 Aug 2020 21:21:20 |
| User entered '17 Oct 2020 00:01' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 03 Aug 2020 21:21:20 |
| User entered '21 Oct 2020 23:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 92' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-31T17:15:22', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'ecef065-ea63-4a9e-a863-12bff2c86db5' | System | 31 Oct 2020 22:15:34 |
| User entered 'No (N)'   | System | 31 Oct 2020 22:15:34 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-31T17:15:25', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'ecef065-ea63-4a9e-a863-12bff2c86db5' | System | 31 Oct 2020 22:15:34 |
| User entered 'No (N)'   | System | 31 Oct 2020 22:15:34 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Date and time of submission](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-31T17:15:30', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'ecef065-ea63-4a9e-a863-12bff2c86db5' | System | 31 Oct 2020 22:15:34 |
| User entered '31 Oct 2020 17:15:30'   | System | 31 Oct 2020 22:15:34 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 03 Aug 2020 21:21:20 |
| User entered '31 Oct 2020 00:01' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 03 Aug 2020 21:21:20 |
| User entered '04 Nov 2020 23:59' | System | 03 Aug 2020 21:21:20 |



**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 99' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-11-07T00:48:28', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fe01dd26-1610-4eca-93ac-e2db6632da69' | System | 07 Nov 2020 06:48:35 |
| User entered 'No (N)'  | System | 07 Nov 2020 06:48:35 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-11-07T00:48:30', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fe01dd26-1610-4eca-93ac-e2db6632da69' | System | 07 Nov 2020 06:48:35 |
| User entered 'No (N)'  | System | 07 Nov 2020 06:48:35 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-11-07T00:48:32', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fe01dd26-1610-4eca-93ac-e2db6632da69' | System | 07 Nov 2020 06:48:35 |
| User entered '07 Nov 2020 00:48:32'  | System | 07 Nov 2020 06:48:35 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 03 Aug 2020 21:21:20 |
| User entered '07 Nov 2020 00:01' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 03 Aug 2020 21:21:20 |
| User entered '11 Nov 2020 23:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                  | User   | Time (GMT)           |
|------------------------|--------|----------------------|
| Data entry locked.     | System | 03 Aug 2020 21:21:20 |
| User entered 'Day 106' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-11-14T00:32:05', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '126d04bb-11b6-40a2-b2a8-2571782e7a3d' | System | 14 Nov 2020 06:32:14 |
| User entered 'No (N)'  | System | 14 Nov 2020 06:32:14 |



**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-11-14T00:32:07', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '126d04bb-11b6-40a2-b2a8-2571782e7a3d' | System | 14 Nov 2020 06:32:14 |
| User entered 'No (N)'  | System | 14 Nov 2020 06:32:14 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-11-14T00:32:09', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '126d04bb-11b6-40a2-b2a8-2571782e7a3d' | System | 14 Nov 2020 06:32:14 |
| User entered '14 Nov 2020 00:32:09'  | System | 14 Nov 2020 06:32:14 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 03 Aug 2020 21:21:20 |
| User entered '14 Nov 2020 00:01' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 03 Aug 2020 21:21:20 |
| User entered '18 Nov 2020 23:59' | System | 03 Aug 2020 21:21:20 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 61' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '30 Sep 2020 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '04 Oct 2020 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 68' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '07 Oct 2020 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '11 Oct 2020 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 75' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '14 Oct 2020 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '18 Oct 2020 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 82' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '21 Oct 2020 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '25 Oct 2020 23:59' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '28 Oct 2020 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '01 Nov 2020 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '04 Nov 2020 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '08 Nov 2020 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '11 Nov 2020 00:01' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '15 Nov 2020 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '18 Nov 2020 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '22 Nov 2020 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '25 Nov 2020 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '29 Nov 2020 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '02 Dec 2020 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '06 Dec 2020 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '09 Dec 2020 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '13 Dec 2020 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '16 Dec 2020 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '20 Dec 2020 23:59' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '23 Dec 2020 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '27 Dec 2020 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '30 Dec 2020 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '03 Jan 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '06 Jan 2021 00:01' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '10 Jan 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '13 Jan 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '17 Jan 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '20 Jan 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '24 Jan 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '27 Jan 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '31 Jan 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '03 Feb 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '07 Feb 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '10 Feb 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '14 Feb 2021 23:59' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '17 Feb 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '21 Feb 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '24 Feb 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '28 Feb 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '03 Mar 2021 00:01' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '07 Mar 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '10 Mar 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '14 Mar 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '17 Mar 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '21 Mar 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '24 Mar 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '28 Mar 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '31 Mar 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '04 Apr 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '07 Apr 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '11 Apr 2021 23:59' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '14 Apr 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '18 Apr 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '21 Apr 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '25 Apr 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '28 Apr 2021 00:01' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '02 May 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '05 May 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '09 May 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '12 May 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '16 May 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '19 May 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '23 May 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '26 May 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '30 May 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '02 Jun 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '06 Jun 2021 23:59' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '09 Jun 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '13 Jun 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '16 Jun 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '20 Jun 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '23 Jun 2021 00:01' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '27 Jun 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '30 Jun 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '04 Jul 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '07 Jul 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '11 Jul 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '14 Jul 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '18 Jul 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '21 Jul 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '25 Jul 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '28 Jul 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '01 Aug 2021 23:59' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '04 Aug 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '08 Aug 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '11 Aug 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '15 Aug 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '18 Aug 2021 00:01' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '22 Aug 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '25 Aug 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '29 Aug 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '01 Sep 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '05 Sep 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '08 Sep 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '12 Sep 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '15 Sep 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '19 Sep 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '22 Sep 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '26 Sep 2021 23:59' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '29 Sep 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '03 Oct 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '06 Oct 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '10 Oct 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '13 Oct 2021 00:01' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '17 Oct 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '20 Oct 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '24 Oct 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '27 Oct 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '31 Oct 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '03 Nov 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '07 Nov 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '10 Nov 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '14 Nov 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '17 Nov 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '21 Nov 2021 23:59' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '24 Nov 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '28 Nov 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '01 Dec 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '05 Dec 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '08 Dec 2021 00:01' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '12 Dec 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '15 Dec 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '19 Dec 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '22 Dec 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '26 Dec 2021 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '29 Dec 2021 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '02 Jan 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '05 Jan 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '09 Jan 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '12 Jan 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '16 Jan 2022 23:59' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '19 Jan 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '23 Jan 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '26 Jan 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '30 Jan 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '02 Feb 2022 00:01' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '06 Feb 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '09 Feb 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '13 Feb 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '16 Feb 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '20 Feb 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '23 Feb 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '27 Feb 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '02 Mar 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '06 Mar 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '09 Mar 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '13 Mar 2022 23:59' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '16 Mar 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '20 Mar 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '23 Mar 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '27 Mar 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '30 Mar 2022 00:01' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '03 Apr 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '06 Apr 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '10 Apr 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '13 Apr 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '17 Apr 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '20 Apr 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '24 Apr 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '27 Apr 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '01 May 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '04 May 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '08 May 2022 23:59' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '11 May 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '15 May 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '18 May 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '22 May 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '25 May 2022 00:01' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '29 May 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '01 Jun 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '05 Jun 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '08 Jun 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '12 Jun 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '15 Jun 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '19 Jun 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '22 Jun 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '26 Jun 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '29 Jun 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '03 Jul 2022 23:59' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '06 Jul 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '10 Jul 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '13 Jul 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '17 Jul 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '20 Jul 2022 00:01' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '24 Jul 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '27 Jul 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '31 Jul 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '03 Aug 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '07 Aug 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '10 Aug 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '14 Aug 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '17 Aug 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '21 Aug 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '24 Aug 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '28 Aug 2022 23:59' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '31 Aug 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '04 Sep 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '07 Sep 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '11 Sep 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '14 Sep 2022 00:01' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '18 Sep 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '21 Sep 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '25 Sep 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '28 Sep 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '02 Oct 2022 23:59' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 12:03:44 |



**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '05 Oct 2022 00:01' | System | 19 Nov 2020 12:03:44 |

**US3212013**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:46:15**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 12:03:44 |
| Amendment Manager: User entered '09 Oct 2022 23:59' | System | 19 Nov 2020 12:03:44 |

US3212013

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:46:15

[Visit Date](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).                                | (b) (4), (b) (6)                 | 19 Nov 2020 08:24:22 |
| Query 'Data is required. Please complete.' answered with 'No Visit done on this date' (Site from System). | (b) (4), (b) (6)                 | 28 Oct 2020 22:35:04 |
| User opened query 'Data is required. Please complete.' (Site from System).                                | System                           | 28 Oct 2020 22:34:53 |
| User entered empty; reason for change Data Entry Error  | (b) (4), (b) (6)                 | 28 Oct 2020 22:34:53 |
| User entered '8 Sep 2020'   | Heather Leary (b) (4)<br>(b) (4) | 16 Oct 2020 19:05:16 |

US3212013

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:46:15

Physical Exam

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User closed query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from System). | System                | 28 Oct 2020 22:34:53 |
| User opened query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from System). | System                | 16 Oct 2020 19:59:15 |
| User closed query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from System). | System                | 16 Oct 2020 19:58:39 |
| User opened query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from System). | System                | 16 Oct 2020 19:56:22 |
| User entered '0' reason for change: Data Entry Error  | Afifah Ayub (b) (4)   | 16 Oct 2020 19:56:22 |
| User closed query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from System). | System                | 16 Oct 2020 19:55:44 |
| User entered '1' reason for change: Data Entry Error  | Afifah Ayub (b) (4)   | 16 Oct 2020 19:55:44 |
| User opened query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from System). | System                | 16 Oct 2020 19:05:16 |
| User entered '0'  | Heather Leary (b) (4) | 16 Oct 2020 19:05:16 |

US3212013

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:46:15

[Vital Signs](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| User entered '0' reason for change: Data Entry Error | Afifah Ayub (b) (4)           | 16 Oct 2020 19:59:15 |
| User entered '1' reason for change: Data Entry Error | (b) (4) Afifah Ayub (b) (4)   | 16 Oct 2020 19:58:39 |
| User entered '0' reason for change: Data Entry Error | (b) (4) Afifah Ayub (b) (4)   | 16 Oct 2020 19:56:22 |
| User entered '1' reason for change: Data Entry Error | (b) (4) Afifah Ayub (b) (4)   | 16 Oct 2020 19:55:44 |
| User entered '0'                                     | (b) (4) Heather Leary (b) (4) | 16 Oct 2020 19:05:16 |

US3212013

Folder: **Unscheduled 08 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **26 Nov 2020 10:46:15**

[Immunogenicity Assessment](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User entered '0' reason for change: Data Entry Error | Afifah Ayub (b) (4)              | 16 Oct 2020 19:56:22 |
| User entered '1' reason for change: Data Entry Error | (b) (4)<br>Afifah Ayub (b) (4)   | 16 Oct 2020 19:55:44 |
| User entered '0'                                     | (b) (4)<br>Heather Leary (b) (4) | 16 Oct 2020 19:05:16 |

US3212013

Folder: Unscheduled 08 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:46:15

[Pregnancy Test](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| User closed query 'Participant is Female and not of Childbearing Potential. Please uncheck.' (Site from System). | System                | 16 Oct 2020 19:55:49 |
| User entered '0' reason for change: Data Entry Error   | Afifah Ayub (b) (4)   | 16 Oct 2020 19:55:49 |
| User opened query 'Participant is Female and not of Childbearing Potential. Please uncheck.' (Site from System). | (b) (4)               |                      |
|  | System                | 16 Oct 2020 19:55:44 |
| User entered '1' reason for change: Data Entry Error   | System                |                      |
|  | Afifah Ayub (b) (4)   | 16 Oct 2020 19:55:44 |
| User entered '0'   | (b) (4)               |                      |
|  | Heather Leary (b) (4) | 16 Oct 2020 19:05:16 |
|  | (b) (4)               |                      |

US3212013

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

Were vital signs assessed?

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).  | (b) (4), (b) (6)    | 19 Nov 2020 08:24:05 |
| Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).   | Afifah Ayub (b) (4) | 16 Oct 2020 19:59:08 |
| User opened query 'Data is required. Please complete.' (Site from System).  | (b) (4)             |                      |
| User opened query 'Data is required. Please complete.' (Site from System).  | System              | 16 Oct 2020 19:59:00 |
| User entered empty; reason for change Data Entry Error  | Afifah Ayub (b) (4) | 16 Oct 2020 19:59:00 |
| User closed query 'Data is required. Please complete.' (Site from System).  | (b) (4)             |                      |
| Query 'Data is required. Please complete.' answered by data change (Site from System).  | System              | 16 Oct 2020 19:58:48 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | Afifah Ayub (b) (4) | 16 Oct 2020 19:58:48 |
| User opened query 'Data is required. Please complete.' (Site from System).  | (b) (4)             |                      |
| User opened query 'Data is required. Please complete.' (Site from System).  | System              | 16 Oct 2020 19:56:30 |
| User closed query 'Response to were vital signs assessed is No for this unscheduled visit. Please change to Yes or remove this unscheduled Vital Signs form.' (Site from System). | System              | 16 Oct 2020 19:56:30 |
| User entered empty; reason for change Data Entry Error  | Afifah Ayub (b) (4) | 16 Oct 2020 19:56:30 |
| User opened query 'Response to were vital signs assessed is No for this unscheduled visit. Please change to Yes or remove this unscheduled Vital Signs form.' (Site from System). | (b) (4)             |                      |
| User opened query 'Response to were vital signs assessed is No for this unscheduled visit. Please change to Yes or remove this unscheduled Vital Signs form.' (Site from System). | System              | 16 Oct 2020 19:55:59 |
| User entered 'No (N)'   | Afifah Ayub (b) (4) | 16 Oct 2020 19:55:59 |
|   | (b) (4)             |                      |



**US3212013**

**Folder: Unscheduled 08 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

**Date of assessment** (*dd MMM yyyy*)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System). | System                         | 16 Oct 2020 19:59:00 |
| User opened query 'Data is required. Please provide.' (Site from System). | System                         | 16 Oct 2020 19:58:48 |
| User entered empty.   | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 19:55:59 |

**US3212013**

**Folder: Unscheduled 08 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Time of assessment \(00:00-23:59\)](#)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).             | System                         | 16 Oct 2020 19:59:00 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System                         | 16 Oct 2020 19:59:00 |
| User opened query 'Data is required. Please provide.' (Site from System).             | System                         | 16 Oct 2020 19:58:48 |
| User entered empty.   | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 19:55:59 |

**US3212013**

**Folder: Unscheduled 08 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Vital Signs Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Oct 2020 19:55:59 |

**US3212013**

**Folder: Unscheduled 08 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Temperature \(xxx.x\)](#)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).             | System                         | 16 Oct 2020 19:59:00 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System                         | 16 Oct 2020 19:59:00 |
| User opened query 'Data is required. Please provide.' (Site from System).             | System                         | 16 Oct 2020 19:58:48 |
| User entered empty.   | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 19:55:59 |

US3212013

Folder: Unscheduled 08 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

[Route of measurement](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 19:55:59 |

**US3212013**

**Folder: Unscheduled 08 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[If Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 19:55:59 |

**US3212013**

**Folder: Unscheduled 08 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Pulse \(xxx\)](#)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).             | System                         | 16 Oct 2020 19:59:00 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System                         | 16 Oct 2020 19:59:00 |
| User opened query 'Data is required. Please provide.' (Site from System).             | System                         | 16 Oct 2020 19:58:48 |
| User entered empty.   | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 19:55:59 |

**US3212013**

**Folder: Unscheduled 08 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Oct 2020 19:55:59 |



**US3212013**

**Folder: Unscheduled 08 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Respiratory Rate \(xxx\)](#)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).             | System                         | 16 Oct 2020 19:59:00 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System                         | 16 Oct 2020 19:59:00 |
| User opened query 'Data is required. Please provide.' (Site from System).             | System                         | 16 Oct 2020 19:58:48 |
| User entered empty.   | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 19:55:59 |

**US3212013**

**Folder: Unscheduled 08 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Respiratory Rate units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Oct 2020 19:55:59 |

**US3212013**

**Folder: Unscheduled 08 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Systolic Blood Pressure \(xxx\)](#)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).             | System                         | 16 Oct 2020 19:59:00 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System                         | 16 Oct 2020 19:59:00 |
| User opened query 'Data is required. Please provide.' (Site from System).             | System                         | 16 Oct 2020 19:58:48 |
| User entered empty.   | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 19:55:59 |

**US3212013**

**Folder: Unscheduled 08 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Oct 2020 19:55:59 |

**US3212013**

**Folder: Unscheduled 08 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).             | System                         | 16 Oct 2020 19:59:00 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System                         | 16 Oct 2020 19:59:00 |
| User opened query 'Data is required. Please provide.' (Site from System).             | System                         | 16 Oct 2020 19:58:48 |
| User entered empty.   | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 19:55:59 |

**US3212013**

**Folder: Unscheduled 08 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Oct 2020 19:55:59 |

**US3212013**

**Folder: Unscheduled 15 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 26 Nov 2020 10:46:15**

[Visit Date](#)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).                                      | (b) (4), (b) (6)               | 19 Nov 2020 08:25:29 |
| Query 'Data is required. Please complete.' answered with 'Visit not performed on this date' (Site from System). | (b) (4), (b) (6)               | 28 Oct 2020 22:36:16 |
| User opened query 'Data is required. Please complete.' (Site from System).                                      | System                         | 28 Oct 2020 22:36:05 |
| User entered empty; reason for change Data Entry Error  | (b) (4), (b) (6)               | 28 Oct 2020 22:36:05 |
| User entered '15 Sep 2020'  | Afifah Ayub (b) (4)<br>(b) (4) | 22 Oct 2020 17:08:46 |

**US3212013**

**Folder: Unscheduled 15 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 26 Nov 2020 10:46:15**

[Physical Exam](#)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User closed query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from System). | System                         | 28 Oct 2020 22:36:05 |
| User opened query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from System). | System                         | 22 Oct 2020 17:08:46 |
| User entered '0'  | Afifah Ayub (b) (4)<br>(b) (4) | 22 Oct 2020 17:08:46 |



**US3212013**

**Folder: Unscheduled 15 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 26 Nov 2020 10:46:15**

[Vital Signs](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 22 Oct 2020 17:08:46 |

US3212013

Folder: Unscheduled 15 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:46:15

[Immunogenicity Assessment](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 22 Oct 2020 17:08:46 |

**US3212013**

**Folder: Unscheduled 15 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 26 Nov 2020 10:46:15**

[Pregnancy Test](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 22 Oct 2020 17:08:46 |

US3212013

Folder: **Unscheduled 29 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **26 Nov 2020 10:46:15**

[Visit Date](#)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| Query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, however please confirm if sample collected on 31AUG2020 and update the Unscheduled visit form. thank you.' answered with 'yes all samples collected on 31AUG2020' (Site from DM).  | Reagan Reed (b) (4) | 23 Nov 2020 21:14:19 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, however please confirm if sample collected on 31AUG2020 and update the Unscheduled visit form. thank you.' (Site from DM).   | (b) (4), (b) (6)    | 20 Nov 2020 07:02:59 |
| User closed query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 31AUG2020 is reported under Unscheduled visit in PPD Central lab, however the same is missing in EDC. Please review and update the details under appropriate visit. Else clarify, thank you.' (Site from DM).   | (b) (4), (b) (6)    | 20 Nov 2020 07:02:59 |
| Query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 31AUG2020 is reported under Unscheduled visit in PPD Central lab, however the same is missing in EDC. Please review and update the details under appropriate visit. Else clarify, thank you.' answered with 'samples collected and the subject noted she received 3 units of blood in a transfusion, her dose 2 was delayed. but the samples had been collected ' (Site from DM). | Reagan Reed (b) (4) | 18 Nov 2020 16:49:31 |
| User opened query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 31AUG2020 is reported under Unscheduled visit in PPD Central lab, however the same is missing in EDC. Please review and update the details under appropriate visit. Else clarify, thank you.' (Site from DM).   | (b) (4), (b) (6)    | 18 Nov 2020 06:09:02 |
| Query 'Per GCL Lab Reconciliation: Sample dated 07OCT2020 is recorded under Unscheduled visit reported in PPD Central lab; however this Unscheduled visit is not in EDC. Please review update as appropriate, else clarify.' answered with 'An unscheduled visit was done to collect NP swab. Please clarify your query.' (Site from DM).   | Reagan Reed (b) (4) | 06 Nov 2020 15:01:32 |

v6.020 DTW (1102)

1643 of 2347

**US3212013**

**Folder: Unscheduled 29 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 26 Nov 2020 10:46:15**

[Visit Date](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User opened query 'Per GCL Lab Reconciliation: Sample dated 07OCT2020 is recorded under Unscheduled visit reported in PPD Central lab; however this Unscheduled visit is not in EDC. Please review update as appropriate, else clarify.' (Site from DM). | (b) (4), (b) (6)               | 29 Oct 2020 18:26:20 |
| User entered '29 Sep 2020'   | Afifah Ayub (b) (4)<br>(b) (4) | 12 Oct 2020 15:51:48 |

**US3212013**

**Folder: Unscheduled 29 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 26 Nov 2020 10:46:15**

[Physical Exam](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered 'I' | Afifah Ayub (b) (4)<br>(b) (4) | 12 Oct 2020 15:51:48 |

**US3212013**

**Folder: Unscheduled 29 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 26 Nov 2020 10:46:15**

[Vital Signs](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '1' | Afifah Ayub (b) (4)<br>(b) (4) | 12 Oct 2020 15:51:48 |

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:46:15

[Immunogenicity Assessment](#)

| Audit  | User                                      | Time (GMT)           |
|--|---|----------------------|
| User entered '0' reason for change: Data Entry Error | Afifah Ayub (b) (4)                       | 12 Oct 2020 15:53:29 |
| User entered '1'                                     | (b) (4)<br>Afifah Ayub (b) (4)<br>(b) (4) | 12 Oct 2020 15:51:48 |



US3212013

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:46:15

[Pregnancy Test](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 12 Oct 2020 15:51:48 |

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

[Were vital signs assessed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Afifah Ayub (b) (4)<br>(b) (4) | 12 Oct 2020 15:52:17 |

**US3212013**

**Folder: Unscheduled 29 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '29 Sep 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 12 Oct 2020 15:52:17 |

**US3212013**

**Folder: Unscheduled 29 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

**Time of assessment (00:00-23:59)**

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| User entered '14:47' | Afifah Ayub (b) (4)<br>(b) (4) | 12 Oct 2020 15:52:17 |

**US3212013**

**Folder: Unscheduled 29 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 14:47' | System | 12 Oct 2020 15:52:17 |

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

Temperature (xxx.x)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered '97.3' F | Afifah Ayub (b) (4)<br>(b) (4) | 12 Oct 2020 15:52:17 |

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

[Route of measurement](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (Oral)' | Afifah Ayub (b) (4)<br>(b) (4) | 12 Oct 2020 15:52:17 |

**US3212013**

**Folder: Unscheduled 29 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[If Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 12 Oct 2020 15:52:17 |



US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

[Pulse \(xxx\)](#)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '83' | Afifah Ayub (b) (4)<br>(b) (4) | 12 Oct 2020 15:52:17 |

**US3212013**

**Folder: Unscheduled 29 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 12 Oct 2020 15:52:17 |

US3212013

Folder: **Unscheduled 29 Sep 2020**

Form: **Vital Signs**

Generated On: **26 Nov 2020 10:46:15**

[Respiratory Rate \(xxx\)](#)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '15' | Afifah Ayub (b) (4)<br>(b) (4) | 12 Oct 2020 15:52:17 |

**US3212013**

**Folder: Unscheduled 29 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 12 Oct 2020 15:52:17 |

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

Systolic Blood Pressure (xxx)

| Audit              | User                           | Time (GMT)           |
|--------------------|--------------------------------|----------------------|
| User entered '126' | Afifah Ayub (b) (4)<br>(b) (4) | 12 Oct 2020 15:52:17 |

**US3212013**

**Folder: Unscheduled 29 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 12 Oct 2020 15:52:17 |

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:46:15

Diastolic Blood Pressure (xxx)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '84' | Afifah Ayub (b) (4)<br>(b) (4) | 12 Oct 2020 15:52:17 |

**US3212013**

**Folder: Unscheduled 29 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:46:15**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 12 Oct 2020 15:52:17 |



US3212013

Folder: Unscheduled 29 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:15

Was the physical examination performed?

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Afifah Ayub (b) (4)<br>(b) (4) | 12 Oct 2020 15:52:27 |

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 10:46:15

Date of examination (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '29 Sep 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 12 Oct 2020 15:52:27 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 26 Nov 2020 10:46:15**

[Did the participant experience any adverse events?](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)                 | 14 Oct 2020 15:04:38 |
| User entered 'Yes (Y)' reason for change: New Information | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:37:22 |
| User entered 'No (N)'                                     | Heather Leary (b) (4)<br>(b) (4) | 05 Aug 2020 14:01:56 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[AEID](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 15:05:09 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 15:50:42 |
| User entered<br>'USA-US115-2020-mRNA-1273-P301000003' | System           | 01 Sep 2020 15:50:28 |
| User entered 'New'                                    | (b) (4), (b) (6) | 01 Sep 2020 15:50:28 |

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:15

[Adverse event](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User closed query 'PV Query: Please provide the results of any diagnostic tests (i.e. pelvic ultrasound, endometrial biopsy, etc). ' (Site from Safety).  | (b) (4), (b) (6)                 | 27 Oct 2020 14:28:41 |
| User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Uterine haemorrhage, LLT: Uterine bleeding - version MedDRA\23.0. | Coder Import (b) (4)<br>(b) (4)  | 26 Oct 2020 20:28:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.   | Coder Import (b) (4)<br>(b) (4)  | 26 Oct 2020 20:28:39 |
| Data point term sent to Coder   | System                           | 26 Oct 2020 20:27:15 |
| DataPoint Un-verified.  | Afifah Ayub (b) (4)<br>(b) (4)   | 26 Oct 2020 20:26:54 |
| Coding entries removed.   | Afifah Ayub (b) (4)<br>(b) (4)   | 26 Oct 2020 20:26:54 |
| User entered 'abnormal UTERINE BLEEDING' reason for change: Data Entry Error  | Afifah Ayub (b) (4)<br>(b) (4)   | 26 Oct 2020 20:26:54 |
| Query 'PV Query: Please provide the results of any diagnostic tests (i.e. pelvic ultrasound, endometrial biopsy, etc). ' answered with 'Medical Records not available ' (Site from Safety).                                   | (b) (4), (b) (6)                 | 26 Oct 2020 19:20:12 |
| DataPoint Verified.   | (b) (4), (b) (6)                 | 14 Oct 2020 15:08:59 |
| User opened query 'PV Query: Please provide the results of any diagnostic tests (i.e. pelvic ultrasound, endometrial biopsy, etc). ' (Site from Safety).  | (b) (4), (b) (6)                 | 10 Sep 2020 15:37:54 |
| User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Uterine haemorrhage, LLT: Uterine bleeding - version MedDRA\23.0. | Coder Import (b) (4)<br>(b) (4)  | 31 Aug 2020 21:10:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.   | Coder Import (b) (4)<br>(b) (4)  | 31 Aug 2020 21:10:48 |
| Data point term sent to Coder   | System                           | 31 Aug 2020 21:09:30 |
| Coding entries removed.   | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 21:09:03 |
| User entered 'UTERINE bleeding' reason for change: Data Entry Error   | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 21:09:03 |

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:15

[Adverse event](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User coded data point as SOC: Reproductive system and breast disorders, HLG: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Uterine haemorrhage, LLT: Uterine hemorrhage - version MedDRA\\23.0. | Coder Import (b) (4)  | 31 Aug 2020 20:45:41 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)  | 31 Aug 2020 20:45:41 |
| Data point term sent to Coder   | System                | 31 Aug 2020 20:44:38 |
| User entered 'Uterine Hemorrhage'   | Heather Leary (b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this a medically-attended AE?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 14 Oct 2020 15:09:01 |
| User entered 'Yes (Y)' | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |



**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 14 Oct 2020 15:09:22 |
| User entered 'No (N)' | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 14 Oct 2020 15:09:26 |
| User entered '27 Aug 2020' | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:15

Start time (00:00-23:59)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)      | 14 Oct 2020 15:09:31 |
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). | System                | 31 Aug 2020 20:44:39 |
| User entered empty; reason for change Data Entry Error   | Heather Leary (b) (4) | 31 Aug 2020 20:44:39 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). | (b) (4)               |                      |
| User entered '00:01'   | System                | 31 Aug 2020 20:44:06 |
|  | Heather Leary (b) (4) | 31 Aug 2020 20:44:06 |
|  | (b) (4)               |                      |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[AE start date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered empty.              | System | 31 Aug 2020 20:44:39 |
| User entered '27 Aug 2020 00:01' | System | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Ongoing?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 14 Oct 2020 15:09:33 |
| User entered 'No (N)' | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 14 Oct 2020 15:09:35 |
| User entered '28 Aug 2020' | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:15

End time (00:00-23:59)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 14 Oct 2020 15:09:37 |
| User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System). | System                           | 31 Aug 2020 20:44:39 |
| User entered empty; reason for change Data Entry Error   | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:39 |
| User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System). | System                           | 31 Aug 2020 20:44:06 |
| User entered '12:01'   | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[AE End Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered empty.              | System | 31 Aug 2020 20:44:39 |
| User entered '28 Aug 2020 12:01' | System | 31 Aug 2020 20:44:06 |



US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:15

[Severity](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 14 Oct 2020 15:09:39 |
| User closed query ' PV Query: As the subject required hospitalization, please consider updating intensity from grade 2 to grade 3. If not updated, please clarify in your response. ' (Site from Safety).             | (b) (4), (b) (6)      | 02 Oct 2020 12:30:36 |
| Query ' PV Query: As the subject required hospitalization, please consider updating intensity from grade 2 to grade 3. If not updated, please clarify in your response. ' answered with 'updated' (Site from Safety). | Heather Leary (b) (4) | 01 Oct 2020 20:20:52 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error  | (b) (4)               | 01 Oct 2020 20:20:38 |
| User opened query ' PV Query: As the subject required hospitalization, please consider updating intensity from grade 2 to grade 3. If not updated, please clarify in your response. ' (Site from Safety).             | (b) (4), (b) (6)      | 10 Sep 2020 15:37:36 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)'  | Heather Leary (b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Is the adverse event serious?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 14 Oct 2020 15:09:42 |
| User entered 'Yes (Y)' | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Death](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 15:09:45 |
| User entered '0'    | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Life threatening](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 15:09:47 |
| User entered '0'    | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 15:09:49 |
| User entered '1'    | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 14 Oct 2020 15:09:51 |
| User entered '27 Aug 2020' | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

**Hospital Discharge Date** (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 14 Oct 2020 15:09:53 |
| User entered '28 Aug 2020' | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Admitted to ICU?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 14 Oct 2020 15:10:00 |
| User entered 'No (N)' | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |



**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Number of Days in ICU](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 15:10:02 |
| User entered empty. | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Persistent or significant disability or incapacity](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 15:10:04 |
| User entered '0'    | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Congenital anomaly or birth defect](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 15:10:05 |
| User entered '0'    | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Other medically important event](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 15:10:07 |
| User entered '0'    | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:15

[Relationship to investigational product](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 14 Oct 2020 15:10:08 |
| Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).    | (b) (4), (b) (6)      | 25 Sep 2020 13:16:24 |
| User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System). | System                | 01 Sep 2020 14:29:42 |
| User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System). | System                | 01 Sep 2020 14:29:42 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error  | Afifah Ayub (b) (4)   | 01 Sep 2020 14:29:42 |
| User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System). | (b) (4)               | 31 Aug 2020 20:44:39 |
| User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System). | System                | 31 Aug 2020 20:44:39 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error  | Heather Leary (b) (4) | 31 Aug 2020 20:44:39 |
| User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System). | (b) (4)               | 31 Aug 2020 20:44:06 |
| User entered 'Not Related (NOT RELATED)'  | Heather Leary (b) (4) | 31 Aug 2020 20:44:06 |
|   | (b) (4)               |                      |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Relationship to Study Procedure](#)

| Audit                                    | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                 | 14 Oct 2020 15:10:10 |
| User entered 'Not Related (NOT RELATED)' | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:15

Action taken with investigational product

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User closed query 'PV Query: It was reported study vaccine was delayed in response to the events. Did the subject received second dose of study vaccine? If yes, please provide date.' (Site from Safety).                   | (b) (4), (b) (6)                 | 27 Oct 2020 14:28:45 |
| Query 'PV Query: It was reported study vaccine was delayed in response to the events. Did the subject received second dose of study vaccine? If yes, please provide date.' answered with 'Yes 07Oct2020' (Site from Safety). | (b) (4), (b) (6)                 | 26 Oct 2020 19:50:20 |
| User opened query 'PV Query: It was reported study vaccine was delayed in response to the events. Did the subject received second dose of study vaccine? If yes, please provide date.' (Site from Safety).                   | (b) (4), (b) (6)                 | 23 Oct 2020 16:48:23 |
| User closed query 'Per source, dose was delayed. Please verify and update accordingly. ' (Site from CRA).  | (b) (4), (b) (6)                 | 23 Oct 2020 14:38:14 |
| DataPoint Verified.  | (b) (4), (b) (6)                 | 23 Oct 2020 14:38:10 |
| Query 'Per source, dose was delayed. Please verify and update accordingly. ' answered with 'UPDATED' (Site from CRA).  | Heather Leary (b) (4)<br>(b) (4) | 15 Oct 2020 19:19:37 |
| User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error   | Heather Leary (b) (4)<br>(b) (4) | 15 Oct 2020 19:19:28 |
| User opened query 'Per source, dose was delayed. Please verify and update accordingly. ' (Site from CRA).  | (b) (4), (b) (6)                 | 14 Oct 2020 15:26:52 |
| DataPoint Un-verified.   | (b) (4), (b) (6)                 | 14 Oct 2020 15:26:15 |
| DataPoint Verified.  | (b) (4), (b) (6)                 | 14 Oct 2020 15:10:12 |
| Query 'Per ETRTR: Please confirm rationale for IP Withdrawn. If data entry error, please amend, thanks.' canceled (Site from CRA).   | (b) (4), (b) (6)                 | 02 Sep 2020 18:26:11 |
| User opened query 'Per ETRTR: Please confirm rationale for IP Withdrawn. If data entry error, please amend, thanks.' (Site from CRA).  | (b) (4), (b) (6)                 | 02 Sep 2020 18:25:23 |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)'   | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[None](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 15:10:13 |
| User entered '0'    | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |



US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:15

[Concomitant Medication](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 14 Oct 2020 15:10:15 |
| User closed query 'PV Query: Please add hormonal contraceptive and any additional treatment to CM eCRF (including dates of administration, dose, units, frequency, route and indication). ' (Site from Safety).                               | (b) (4), (b) (6)      | 02 Oct 2020 12:30:44 |
| Query 'PV Query: Please add hormonal contraceptive and any additional treatment to CM eCRF (including dates of administration, dose, units, frequency, route and indication). ' answered with 'conmeds have been updated' (Site from Safety). | Heather Leary (b) (4) | 01 Oct 2020 20:21:43 |
| User opened query 'PV Query: Please add hormonal contraceptive and any additional treatment to CM eCRF (including dates of administration, dose, units, frequency, route and indication). ' (Site from Safety).                               | (b) (4), (b) (6)      | 10 Sep 2020 15:38:16 |
| User entered 'I'  | Heather Leary (b) (4) | 31 Aug 2020 20:44:06 |

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:15

[Concomitant Procedure](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). DataPoint Verified.              | (b) (4), (b) (6)      | 19 Oct 2020 16:10:15 |
|  | (b) (4), (b) (6)      | 14 Oct 2020 15:10:20 |
| Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'procedures have been updated' (Site from DM). | Heather Leary (b) (4) | 01 Oct 2020 20:22:07 |
| User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).                                  | (b) (4), (b) (6)      | 23 Sep 2020 03:39:20 |
| User entered 'I'   | Heather Leary (b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Outcome](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)                 | 14 Oct 2020 15:10:25 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 15:10:26 |
| User entered empty. | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:44:06 |

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:15

[Narrative](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User closed query 'PV Query: The following was provided in a query response, "subject had episodes of severe or prolonged uterine bleeding prior to blinded study medication administration". Please add "episodes of severe or prolonged uterine bleeding" to medical history in EDC.' (Site from Safety).  | (b) (4), (b) (6)    | 24 Nov 2020 13:00:23 |
| Query 'PV Query: The following was provided in a query response, "subject had episodes of severe or prolonged uterine bleeding prior to blinded study medication administration". Please add "episodes of severe or prolonged uterine bleeding" to medical history in EDC.' answered with 'Subject has Fibroids noted in Medical History.' (Site from Safety). | Reagan Reed (b) (4) | 23 Nov 2020 21:52:47 |
| User opened query 'PV Query: The following was provided in a query response, "subject had episodes of severe or prolonged uterine bleeding prior to blinded study medication administration". Please add "episodes of severe or prolonged uterine bleeding" to medical history in EDC.' (Site from Safety).  | (b) (4), (b) (6)    | 23 Nov 2020 19:15:36 |
| User closed query 'PV Query: Please add the episodes of severe, prolonged uterine bleeding reported in query response to the subject's medical history.' (Site from Safety).   | (b) (4), (b) (6)    | 17 Nov 2020 15:03:28 |
| Query 'PV Query: Please add the episodes of severe, prolonged uterine bleeding reported in query response to the subject's medical history.' answered with 'Please clarify this query - AE is of "ABNORMAL" Uterine bleeding is added.' (Site from Safety).  | (b) (4), (b) (6)    | 16 Nov 2020 22:09:13 |
| User opened query 'PV Query: Please add the episodes of severe, prolonged uterine bleeding reported in query response to the subject's medical history.' (Site from Safety).   | (b) (4), (b) (6)    | 04 Nov 2020 20:57:53 |
| User closed query 'PV Query: Did the subject receive the second dose of IP administration?' (Site from Safety).  | (b) (4), (b) (6)    | 27 Oct 2020 14:29:00 |
| User closed query 'PV Query: Please clarify if the subject had episodes of severe or prolonged uterine bleeding prior to blinded study medication administration?' (Site from Safety).   | (b) (4), (b) (6)    | 27 Oct 2020 14:28:59 |

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:15

[Narrative](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User closed query 'PV query: What was the etiology/cause of the uterine bleeding (i.e. uterine fibroids, hormonal imbalance, etc) ' (Site from Safety).   | (b) (4), (b) (6) | 27 Oct 2020 14:28:57 |
| User closed query 'PV Query: Please provide the subject's hemoglobin and hematocrit pre and post blood transfusion (including units and reference range). ' (Site from Safety).   | (b) (4), (b) (6) | 27 Oct 2020 14:28:56 |
| User closed query 'PV Query: Please confirm if all bleeding had subsided at event resolution and provide update on subject's current status. ' (Site from Safety).  | (b) (4), (b) (6) | 27 Oct 2020 14:28:53 |
| Query 'PV Query: Did the subject receive the second dose of IP administration?' answered with 'Yes' (Site from Safety).   | (b) (4), (b) (6) | 26 Oct 2020 20:12:04 |
| Query 'PV Query: Please clarify if the subject had episodes of severe or prolonged uterine bleeding prior to blinded study medication administration?' answered with 'Yes- subject had episodes of severe or prolonged uterine bleeding prior to blinded study medication administration' (Site from Safety). | (b) (4), (b) (6) | 26 Oct 2020 20:11:21 |
| Query 'PV query: What was the etiology/cause of the uterine bleeding (i.e. uterine fibroids, hormonal imbalance, etc) ' answered with 'Uterine Fibroids' (Site from Safety).  | (b) (4), (b) (6) | 26 Oct 2020 20:11:08 |
| Query 'PV Query: Please provide the subject's hemoglobin and hematocrit pre and post blood transfusion (including units and reference range). ' answered with 'Pre Hb - 6.3, Post transfusion Hb - 10' (Site from Safety).  | (b) (4), (b) (6) | 26 Oct 2020 20:10:49 |
| Query 'PV Query: Please confirm if all bleeding had subsided at event resolution and provide update on subject's current status. ' answered with 'Yes - all bleeding subsided, healing well from hysterectomy. Hb level was 10 ug/dl at last visit. ' (Site from Safety).                                     | (b) (4), (b) (6) | 26 Oct 2020 19:52:32 |
| User opened query 'PV Query: Did the subject receive the second dose of IP administration?' (Site from Safety).   | (b) (4), (b) (6) | 23 Oct 2020 16:48:05 |
| User closed query 'Per source, IP was not withdrawn but delayed. Please verify and update accordingly. ' (Site from CRA).   | (b) (4), (b) (6) | 23 Oct 2020 14:38:39 |

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:15

[Narrative](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 23 Oct 2020 14:38:34 |
| User closed query 'Per DM CLR: As per SAE narrative, "SHE WAS ADMITTED TO HOSPITAL AND RECEIVED 3 PINTS OF TRANSFUSED BLOOD", however, please note that there is no ConProc recorded in ConProc eCRF page. Please reconcile and update as appropriate, otherwise provide clarification.' (Site from DM).  | (b) (4), (b) (6)      | 19 Oct 2020 16:10:22 |
| User closed query 'Per DM CLR: As per SAE narrative, "PATIENT HAS A HISTORY OF UTERINE FIBROIDS", however, please note that this MH condition is not recorded in MH eCRF page. Please reconcile and update as appropriate, otherwise provide clarification.' (Site from DM).  | (b) (4), (b) (6)      | 19 Oct 2020 16:10:17 |
| Query 'Per source, IP was not withdrawn but delayed. Please verify and update accordingly. ' answered with 'UPDATED' (Site from CRA).   | Heather Leary (b) (4) | 15 Oct 2020 19:20:09 |
| User entered 'PATIENT HAS A HISTORY OF UTERINE FIBROIDS. ON 27AUG2020 SHE PRESENTED TO MEMORIAL HERMANN HOSPITAL WITH UTERINE HEMORRHAGE. SHE WAS ADMITTED TO HOSPITAL AND RECEIVED 3 PINTS OF TRANSFUSED BLOOD. SHE WAS PRESCRIBED HORMONAL CONTRACEPTION AS WELL. SHE WAS DISCHARGED ON 28AUG2020. RECORDS WILL BE REQUESTED BY SITE. IP IS BEING DELAYED DUE TO PARTICIPANT'S RECEIVING BLOOD TRANSFUSIONS.' reason for change: Data Entry Error | Heather Leary (b) (4) | 15 Oct 2020 19:20:01 |
| User opened query 'Per source, IP was not withdrawn but delayed. Please verify and update accordingly. ' (Site from CRA).   | (b) (4), (b) (6)      | 14 Oct 2020 15:12:12 |
| User opened query 'PV Query: Please clarify if the subject had episodes of severe or prolonged uterine bleeding prior to blinded study medication administration?' (Site from Safety).  | (b) (4), (b) (6)      | 09 Oct 2020 13:00:02 |
| User closed query 'PV query: Please add uterine fibroids to the subject's medical history eCRF page with applicable dates. ' (Site from Safety).  | (b) (4), (b) (6)      | 02 Oct 2020 12:30:53 |

v6.020 DTW (1102)

1702 of 2347

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:15

[Narrative](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Query 'Per DM CLR: As per SAE narrative, "SHE WAS ADMITTED TO HOSPITAL AND RECEIVED 3 PINTS OF TRANSFUSED BLOOD", however, please note tthat there is no ConProc recorded in ConProc eCRF page. Please reconcile and update as appropriate, otherwise provide clarification.' answered with 'ConProc were updated' (Site from DM). | Heather Leary (b) (4) | 01 Oct 2020 20:23:40 |
| Query 'Per DM CLR: As per SAE narrative, "PATIENT HAS A HISTORY OF UTERINE FIBROIDS", however, please note that this MH condition is not recorded in MH eCRF page. Please reconcile and update as appropriate, otherwise provide clarification.' answered with 'MH updated' (Site from DM).  | Heather Leary (b) (4) | 01 Oct 2020 20:23:31 |
| Query 'PV query: Please add uterine fibroids to the subject's medical history eCRF page with applicable dates. ' answered with 'entry added' (Site from Safety).   | Heather Leary (b) (4) | 01 Oct 2020 20:23:15 |
| User opened query 'Per DM CLR: As per SAE narrative, "SHE WAS ADMITTED TO HOSPITAL AND RECEIVED 3 PINTS OF TRANSFUSED BLOOD", however, please note tthat there is no ConProc recorded in ConProc eCRF page. Please reconcile and update as appropriate, otherwise provide clarification.' (Site from DM).                          | (b) (4), (b) (6)      | 23 Sep 2020 03:40:55 |
| User opened query 'Per DM CLR: As per SAE narrative, "PATIENT HAS A HISTORY OF UTERINE FIBROIDS", however, please note that this MH condition is not recorded in MH eCRF page. Please reconcile and update as appropriate, otherwise provide clarification.' (Site from DM).   | (b) (4), (b) (6)      | 23 Sep 2020 03:40:19 |
| User opened query 'PV query: What was the etiology/cause of the uterine bleeding (i.e. uterine fibroids, hormonal imbalance, etc) ' (Site from Safety).  | (b) (4), (b) (6)      | 10 Sep 2020 15:39:28 |
| User opened query 'PV Query: Please provide the subject's hemoglobin and hematocrit pre and post blood transfusion (including units and reference range). ' (Site from Safety).  | (b) (4), (b) (6)      | 10 Sep 2020 15:39:10 |



US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:46:15

[Narrative](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User opened query 'PV query: Please add uterine fibroids to the subject's medical history eCRF page with applicable dates. ' (Site from Safety).  | (b) (4), (b) (6)                 | 10 Sep 2020 15:38:53 |
| User opened query 'PV Query: Please confirm if all bleeding had subsided at event resolution and provide update on subject's current status. ' (Site from Safety).  | (b) (4), (b) (6)                 | 10 Sep 2020 15:38:35 |
| Query 'Per ETRTR: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication), thanks.' canceled (Site from CRA).   | (b) (4), (b) (6)                 | 06 Sep 2020 18:21:12 |
| Query 'Per ETRTR: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from CRA).   | (b) (4), (b) (6)                 | 06 Sep 2020 18:21:10 |
| User opened query 'Per ETRTR: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication), thanks.' (Site from CRA).  | (b) (4), (b) (6)                 | 02 Sep 2020 18:28:00 |
| User opened query 'Per ETRTR: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from CRA).  | (b) (4), (b) (6)                 | 02 Sep 2020 18:27:04 |
| User entered 'PATIENT HAS A HISTORY OF UTERINE FIBROIDS. ON 27AUG2020 SHE PRESENTED TO MEMORIAL HERMANN HOSPITAL WITH UTERINE HEMORRHAGE. SHE WAS ADMITTED TO HOSPITAL AND RECEIVED 3 PINTS OF TRANSFUSED BLOOD. SHE WAS PRESCRIBED HORMONAL CONTRACEPTION AS WELL. SHE WAS DISCHARGED ON 28AUG2020. RECORDS WILL BE REQUESTED BY SITE. IP IS BEING WITHDRAWN DUE TO PARTICIPANT'S RECEIVING BLOOD TRANSFUSIONS.' reason for change: Data Entry Error | Heather Leary (b) (4)<br>(b) (4) | 31 Aug 2020 20:45:24 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Narrative](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| User entered 'Patient has a history of uterine fibroids. Heather Leary (b) (4) On 27AUG2020 she presented to Memorial Hermann (b) (4) hospital with uterine hemorrhage. She was admitted to hospital and received 3 pints of transfused blood. She was prescribed hormonal contraception as well. She was discharged on 28AUG2020. Records will be requested by site.' | Heather Leary (b) (4) | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 31 Aug 2020 20:44:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 31 Aug 2020 20:44:06 |

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:46:15

[Adverse event](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Oct 2020 16:26:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4) | 20 Oct 2020 16:26:40 |
| Data point term sent to Coder  | System               | 20 Oct 2020 16:25:50 |
| User entered 'Urinary tract infection'   | Reagan Reed (b) (4)  | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this a medically-attended AE?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |



**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '12 Oct 2020' | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:46:15

[Start time \(00:00-23:59\)](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). | System              | 20 Oct 2020 16:25:17 |
| User entered empty; reason for change Data Entry Error   | Reagan Reed (b) (4) | 20 Oct 2020 16:25:17 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). | System              | 20 Oct 2020 16:25:06 |
| User entered '12:00'   | Reagan Reed (b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[AE start date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered empty.              | System | 20 Oct 2020 16:25:17 |
| User entered '12 Oct 2020 12:00' | System | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Ongoing?](#)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 05 Nov 2020 14:21:17 |
| User entered 'Yes (Y)'                                    | Reagan Reed (b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User entered '19 Oct 2020' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 05 Nov 2020 14:21:17 |
| User entered empty.  | Reagan Reed (b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[End time \(00:00-23:59\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Oct 2020 16:25:06 |



**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Severity](#)

| Audit                                      | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Is the adverse event serious?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Death](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Life threatening](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Admitted to ICU?](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |



**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Number of Days in ICU](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Persistent or significant disability or incapacity](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Congenital anomaly or birth defect](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Other medically important event](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Relationship to investigational product](#)

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:46:15

[Relationship to Study Procedure](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).             | (b) (4), (b) (6)    | 23 Nov 2020 12:54:48 |
| Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' answered with 'updated' (Site from DM). | Reagan Reed (b) (4) | 18 Nov 2020 15:29:52 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error   | Reagan Reed (b) (4) | 18 Nov 2020 15:29:48 |
| User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).             | (b) (4), (b) (6)    | 18 Nov 2020 08:58:09 |
| User entered 'Not Applicable (NOT APPLICABLE)'   | Reagan Reed (b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Action taken with investigational product](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'None (NONE)' | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[None](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |



**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Concomitant Medication](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '1' | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Concomitant Procedure](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Outcome](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 05 Nov 2020 14:21:17 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'                                 | Reagan Reed (b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Narrative](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Reagan Reed (b) (4)<br>(b) (4) | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 20 Oct 2020 16:25:06 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[AEID](#)

| Audit                                 | User             | Time (GMT)           |
|---------------------------------------|------------------|----------------------|
| Reviewed for Safety.                  | (b) (4), (b) (6) | 27 Oct 2020 14:29:42 |
|                                       |                  |                      |
| User entered                          | (b) (4), (b) (6) | 27 Oct 2020 14:29:38 |
| 'USA-US115-2020-mRNA-1273-P301000003' |                  |                      |
|                                       |                  |                      |



US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:46:15

[Adverse event](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User closed query 'Per DM CLR: Please confirm the AE term "WORSENING OF ABNORMAL UTERINE BLEEDING", as there is no associated baseline Med History condition or Sequential Adverse Event noted. Clarify if this condition is an exacerbation of a baseline condition or sequential AE. If so, please add the corresponding condition to the Med History or AE eCRF. Otherwise, consider deleting the term "worsening" from this event.' (Site from DM).                                | (b) (4), (b) (6)                | 24 Nov 2020 14:55:34 |
| Query 'Per DM CLR: Please confirm the AE term "WORSENING OF ABNORMAL UTERINE BLEEDING", as there is no associated baseline Med History condition or Sequential Adverse Event noted. Clarify if this condition is an exacerbation of a baseline condition or sequential AE. If so, please add the corresponding condition to the Med History or AE eCRF. Otherwise, consider deleting the term "worsening" from this event.' answered with 'please see AE line item #1' (Site from DM). | Reagan Reed (b) (4)<br>(b) (4)  | 23 Nov 2020 18:48:09 |
| User opened query 'Per DM CLR: Please confirm the AE term "WORSENING OF ABNORMAL UTERINE BLEEDING", as there is no associated baseline Med History condition or Sequential Adverse Event noted. Clarify if this condition is an exacerbation of a baseline condition or sequential AE. If so, please add the corresponding condition to the Med History or AE eCRF. Otherwise, consider deleting the term "worsening" from this event.' (Site from DM).                                | (b) (4), (b) (6)                | 22 Nov 2020 09:33:30 |
| User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Uterine haemorrhage, LLT: Uterine bleeding - version MedDRA\23.0.  | Coder Import (b) (4)<br>(b) (4) | 26 Oct 2020 21:46:31 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.   | Coder Import (b) (4)<br>(b) (4) | 26 Oct 2020 21:46:31 |
| Data point term sent to Coder  | System                          | 26 Oct 2020 20:29:18 |
| User entered 'Worsening of Abnormal Uterine Bleeding'  | Afifah Ayub (b) (4)<br>(b) (4)  | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this a medically-attended AE?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:46:15

Start date (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '22 Sep 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Start time \(00:00-23:59\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Ongoing?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |



**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '22 Sep 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[End time \(00:00-23:59\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Severity](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered 'Grade 3/Severe (Grade 3/Severe)' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:46:15

[Is the adverse event serious?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Death](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Life threatening](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:46:15

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).             | System                         | 26 Oct 2020 20:49:06 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System). |                                | 26 Oct 2020 20:49:06 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).             | System                         | 26 Oct 2020 20:29:03 |
| User entered '1'  | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |



US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:46:15

Hospital Admission Date (*dd MMM yyyy*)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User entered '22 Sep 2020' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 26 Oct 2020 20:49:06 |
| User entered empty.  | Afifah Ayub (b) (4) | 26 Oct 2020 20:29:03 |

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:46:15

Hospital Discharge Date (dd MMM yyyy)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| User closed query 'PV Query: Please confirm hospital discharge date. Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).  | (b) (4), (b) (6)    | 06 Nov 2020 16:16:27 |
| Query 'PV Query: Please confirm hospital discharge date. Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'kept in hospital overnight for observation discharged next morning' (Site from Safety). | Reagan Reed (b) (4) | 05 Nov 2020 16:19:26 |
| User entered '23 Sep 2020' reason for change: Data Entry Error  | (b) (4)             | 05 Nov 2020 16:19:02 |
| User opened query 'PV Query: Please confirm hospital discharge date. Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).  | (b) (4), (b) (6)    | 04 Nov 2020 20:58:35 |
| User entered '22 Sep 2020' reason for change: Data Entry Error  | Afifah Ayub (b) (4) | 26 Oct 2020 20:49:06 |
| User entered empty.   | Afifah Ayub (b) (4) | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Admitted to ICU?](#)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 26 Oct 2020 20:49:06 |
| User entered empty.                                       | Afifah Ayub (b) (4) | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Number of Days in ICU](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:46:15

[Persistent or significant disability or incapacity](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Congenital anomaly or birth defect](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Other medically important event](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Relationship to investigational product](#)

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |



**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Relationship to Study Procedure](#)

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Action taken with investigational product](#)

| Audit                                      | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered 'Dose Delayed (DOSE DELAYED)' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[None](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:46:15

[Concomitant Medication](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).             | (b) (4), (b) (6)    | 24 Nov 2020 15:00:06 |
| Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM). | Reagan Reed (b) (4) | 23 Nov 2020 21:48:28 |
| User entered '0' reason for change: Data Entry Error   | (b) (4)             | 23 Nov 2020 21:48:24 |
| User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).             | (b) (4), (b) (6)    | 22 Nov 2020 09:33:39 |
| User entered '1'   | Afifah Ayub (b) (4) | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Concomitant Procedure](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered 'I' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Outcome](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 20:29:03 |

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:46:15

[Narrative](#)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).             | System              | 26 Oct 2020 20:29:20 |
| Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System). | System              | 26 Oct 2020 20:29:20 |
| User entered 'Subject underwent hysterectomy for uterine bleeding/fibroids.' reason for change: Data Entry Error    | Afifah Ayub (b) (4) | 26 Oct 2020 20:29:20 |
| User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).             | System              | 26 Oct 2020 20:29:03 |
| User entered empty.   | Afifah Ayub (b) (4) | 26 Oct 2020 20:29:03 |



**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 26 Oct 2020 20:29:03 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 26 Oct 2020 20:49:06 |

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:46:15

[Adverse event](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue infections and inflammations NEC, PT: Plantar fasciitis, LLT: Plantar fasciitis - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 10 Nov 2020 23:51:53 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4) | 10 Nov 2020 23:51:53 |
| Data point term sent to Coder  | System                          | 05 Nov 2020 14:22:47 |
| Coding entries removed.  | Afifah Ayub (b) (4)<br>(b) (4)  | 05 Nov 2020 14:22:18 |
| User entered 'right FOOT PAIN (plantar fasciitis)' reason for change: Data Entry Error   | Afifah Ayub (b) (4)<br>(b) (4)  | 05 Nov 2020 14:22:18 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Foot pain - version MedDRA\\23.0.                      | Coder Import (b) (4)<br>(b) (4) | 29 Oct 2020 20:06:41 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4) | 29 Oct 2020 20:06:41 |
| Data point term sent to Coder  | System                          | 28 Oct 2020 20:36:47 |
| User entered 'foot pain'   | Afifah Ayub (b) (4)<br>(b) (4)  | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this a medically-attended AE?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '22 Oct 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |



**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Start time \(00:00-23:59\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Ongoing?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

**If not Ongoing, end date (*dd MMM yyyy*)**

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[End time \(00:00-23:59\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Severity](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Afifah Ayub (b) (4) | 05 Nov 2020 14:22:18 |
| reason for change: Data Entry Error                | (b) (4)             |                      |
| User entered 'Grade 1/Mild (Grade 1/Mild)'         | Afifah Ayub (b) (4) | 28 Oct 2020 20:35:55 |
|  | (b) (4)             |                      |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Is the adverse event serious?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |



**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Death](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Life threatening](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Admitted to ICU?](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Number of Days in ICU](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Persistent or significant disability or incapacity](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |



**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Congenital anomaly or birth defect](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Other medically important event](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Relationship to investigational product](#)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)'<br>reason for change: Data Entry Error | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:22:18 |
| User entered 'Not Applicable (NOT APPLICABLE)'                                  | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Relationship to Study Procedure](#)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)'<br>reason for change: Data Entry Error | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:22:18 |
| User entered 'Not Applicable (NOT APPLICABLE)'                                  | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Action taken with investigational product](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'None (NONE)' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[None](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Concomitant Medication](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered 'I' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Concomitant Procedure](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |



**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Outcome](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Narrative](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 28 Oct 2020 20:35:55 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 28 Oct 2020 20:35:55 |

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:46:15

[Adverse event](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Candida infections, PT: Vulvovaginal candidiasis, LLT: Vaginal candidiasis - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 05 Nov 2020 14:24:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4) | 05 Nov 2020 14:24:20 |
| Data point term sent to Coder   | System                          | 05 Nov 2020 14:23:48 |
| User entered 'Vaginal Candidiasis'  | Afifah Ayub (b) (4)<br>(b) (4)  | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this a medically-attended AE?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |



**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '20 Oct 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

**Start time (00:00-23:59)**

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Ongoing?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:46:15

If not Ongoing, end date (dd MMM yyyy)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).             | System                         | 05 Nov 2020 16:13:29 |
| Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System). | System                         | 05 Nov 2020 16:13:29 |
| User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).             | System                         | 05 Nov 2020 14:23:46 |
| User entered empty.  | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[End time \(00:00-23:59\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 14:23:46 |



**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Severity](#)

| Audit                                      | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Is the adverse event serious?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Death](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Life threatening](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:46:15

Hospital Admission Date (*dd MMM yyyy*)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:46:15

Hospital Discharge Date (*dd MMM yyyy*)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Admitted to ICU?](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |



**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Number of Days in ICU](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Persistent or significant disability or incapacity](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Congenital anomaly or birth defect](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Other medically important event](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Relationship to investigational product](#)

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Relationship to Study Procedure](#)

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Action taken with investigational product](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered 'Not Applicable (NOT APPLICABLE)' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[None](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |



**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Concomitant Medication](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered 'I' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Concomitant Procedure](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:46:15

[Outcome](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).                     | System                         | 05 Nov 2020 16:13:39 |
| Query 'Data is required. Please complete.' answered by data change (Site from System).         | System                         | 05 Nov 2020 16:13:39 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error | Reagan Reed (b) (4)<br>(b) (4) | 05 Nov 2020 16:13:39 |
| User opened query 'Data is required. Please complete.' (Site from System).                     | System                         | 05 Nov 2020 16:13:29 |
| User entered empty; reason for change Data Entry Error   | Reagan Reed (b) (4)<br>(b) (4) | 05 Nov 2020 16:13:29 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'   | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Narrative](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 05 Nov 2020 14:23:46 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 10:46:15**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 15:33:30 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 03 Aug 2020 21:10:01 |



US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:15

[Name of Medication](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)     | 14 Oct 2020 15:42:31 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: OXYBUTYNIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Aug 2020 16:16:10 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | (b) (4)              | 12 Aug 2020 16:16:10 |
| Data point term sent to Coder   | System               | 03 Aug 2020 21:12:21 |
| User entered 'Oxybutynin'   | (b) (4), (b) (6)     | 03 Aug 2020 21:11:49 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:15

[Prophylaxis](#)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 14 Oct 2020 15:42:32 |
| User closed query 'Per DM CLR: Prophylaxis=YES. However, there is corresponding MH condition that matches this con med and is within the time frame. Please review and verify if this can be changed to NO. if yes, please update accordingly.' (Site from DM).             | (b) (4), (b) (6)               | 30 Sep 2020 14:00:30 |
| Query 'Per DM CLR: Prophylaxis=YES. However, there is corresponding MH condition that matches this con med and is within the time frame. Please review and verify if this can be changed to NO. if yes, please update accordingly.' answered with 'updated' (Site from DM). | Afifah Ayub (b) (4)<br>(b) (4) | 21 Sep 2020 14:59:05 |
| User entered 'No (N)' reason for change: Data Entry Error   | Afifah Ayub (b) (4)<br>(b) (4) | 21 Sep 2020 14:58:53 |
| User opened query 'Per DM CLR: Prophylaxis=YES. However, there is corresponding MH condition that matches this con med and is within the time frame. Please review and verify if this can be changed to NO. if yes, please update accordingly.' (Site from DM).             | (b) (4), (b) (6)               | 18 Sep 2020 09:28:31 |
| User entered 'Yes (Y)'  | (b) (4), (b) (6)               | 03 Aug 2020 21:11:49 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Indication](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| DataPoint Verified.                 | (b) (4), (b) (6) | 14 Oct 2020 15:42:35 |
| User entered 'Urinary Incontinence' | (b) (4), (b) (6) | 03 Aug 2020 21:11:49 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:42:37 |
| User entered '5'    | (b) (4), (b) (6) | 03 Aug 2020 21:11:49 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 15:42:39 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 03 Aug 2020 21:11:49 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:46:15**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:42:41 |
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 21:11:49 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 14 Oct 2020 15:42:43 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 03 Aug 2020 21:11:49 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:46:15**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:42:44 |
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 21:11:49 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 14 Oct 2020 15:42:46 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 03 Aug 2020 21:11:49 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:46:15**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:44:29 |
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 21:11:49 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:15

Start date (dd MMM yyyy)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 15:44:35 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).    | (b) (4), (b) (6) | 03 Aug 2020 23:35:42 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System           | 03 Aug 2020 21:21:20 |
| User entered 'UN UNK 2019'   | (b) (4), (b) (6) | 03 Aug 2020 21:11:49 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:44:40 |
| User entered '0'    | (b) (4), (b) (6) | 03 Aug 2020 21:11:49 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 15:44:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 03 Aug 2020 21:11:49 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:46:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:44:45 |
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 21:11:49 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:46:15

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 15:44:49 |
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:11:49 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Aug 2020 21:11:49 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Aug 2020 21:11:49 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Aug 2020 21:11:49 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:15

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                | 14 Oct 2020 15:46:45 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 14 Oct 2020 12:21:45 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4) | 14 Oct 2020 12:21:45 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE SODIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE SODIUM] - version WHODrug-Global-B3\\202003.       | Coder Import (b) (4)<br>(b) (4) | 15 Sep 2020 21:25:49 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4) | 15 Sep 2020 21:25:49 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE SODIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE SODIUM] - version WHODrug-Global-B3\\202003.       | Coder Import (b) (4)<br>(b) (4) | 04 Aug 2020 13:11:05 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4) | 04 Aug 2020 13:11:05 |
| Data point term sent to Coder  | System                          | 03 Aug 2020 21:14:24 |

v6.020 DTW (1102)

1866 of 2347

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:15

[Name of Medication](#)

| Audit                                 | User             | Time (GMT)           |
|---------------------------------------|------------------|----------------------|
| User entered 'Esmoprazole ( Nexium )' | (b) (4), (b) (6) | 03 Aug 2020 21:13:51 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:15

[Prophylaxis](#)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 14 Oct 2020 15:46:47 |
| User closed query 'Per DM CLR: Prophylaxis=YES. However, there is corresponding MH condition that matches this con med and is within the time frame. Please review and verify if this can be changed to NO. if yes, please update accordingly.' (Site from DM).             | (b) (4), (b) (6)               | 30 Sep 2020 14:00:34 |
| Query 'Per DM CLR: Prophylaxis=YES. However, there is corresponding MH condition that matches this con med and is within the time frame. Please review and verify if this can be changed to NO. if yes, please update accordingly.' answered with 'updated' (Site from DM). | Afifah Ayub (b) (4)<br>(b) (4) | 21 Sep 2020 14:59:29 |
| User entered 'No (N)' reason for change: Data Entry Error   | Afifah Ayub (b) (4)<br>(b) (4) | 21 Sep 2020 14:59:20 |
| User opened query 'Per DM CLR: Prophylaxis=YES. However, there is corresponding MH condition that matches this con med and is within the time frame. Please review and verify if this can be changed to NO. if yes, please update accordingly.' (Site from DM).             | (b) (4), (b) (6)               | 18 Sep 2020 09:25:48 |
| User entered 'Yes (Y)'  | (b) (4), (b) (6)               | 03 Aug 2020 21:13:51 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Indication](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6) | 14 Oct 2020 15:46:49 |
| User entered 'Gastroesophageal Reflux Disease' | (b) (4), (b) (6) | 03 Aug 2020 21:13:51 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:46:52 |
| User entered '20'   | (b) (4), (b) (6) | 03 Aug 2020 21:13:51 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:15

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 15:46:54 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 03 Aug 2020 21:13:51 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:46:15**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:46:56 |
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 21:13:51 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 14 Oct 2020 15:47:00 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 03 Aug 2020 21:13:51 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:46:15**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:47:02 |
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 21:13:51 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 14 Oct 2020 15:47:05 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 03 Aug 2020 21:13:51 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:46:15**

[If route of administration is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:47:07 |
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 21:13:51 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:46:15

Start date (dd MMM yyyy)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 15:47:11 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).    | (b) (4), (b) (6) | 03 Aug 2020 23:35:46 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System           | 03 Aug 2020 21:21:20 |
| User entered 'UN UNK 2019'   | (b) (4), (b) (6) | 03 Aug 2020 21:13:51 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:47:13 |
| User entered '0'    | (b) (4), (b) (6) | 03 Aug 2020 21:13:51 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 15:47:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 03 Aug 2020 21:13:51 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:46:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:47:17 |
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 21:13:51 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 15:47:26 |
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:13:51 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Aug 2020 21:13:51 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Aug 2020 21:13:51 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Aug 2020 21:13:51 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:15

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                | 14 Oct 2020 15:47:41 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE, PRODUCTSYNONYM: FERROUS SULPHATE [FERROUS SULFATE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 03 Aug 2020 23:31:06 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4) | 03 Aug 2020 23:31:06 |
| Data point term sent to Coder  | System                          | 03 Aug 2020 21:15:24 |
| User entered 'Ferrous Sulphate'  | (b) (4), (b) (6)                | 03 Aug 2020 21:15:13 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:15

[Prophylaxis](#)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| User closed query 'Per source, answer is No. Please verify and update accordingly.' (Site from CRA).<br>DataPoint Verified.   | (b) (4), (b) (6)    | 23 Oct 2020 14:39:45 |
|   | (b) (4), (b) (6)    | 23 Oct 2020 14:39:43 |
| Query 'Per source, answer is No. Please verify and update accordingly.' answered with 'updated' (Site from CRA).  | Afifah Ayub (b) (4) | 14 Oct 2020 17:02:18 |
| User entered 'No (N)' reason for change: Data Entry Error   | Afifah Ayub (b) (4) | 14 Oct 2020 17:02:13 |
| User opened query 'Per source, answer is No. Please verify and update accordingly.' (Site from CRA).  | (b) (4), (b) (6)    | 14 Oct 2020 15:51:01 |
| User closed query 'Per DM CLR: Prophylaxis=YES. However, there is corresponding MH condition that matches this con med and is within the time frame. Please review and verify if this can be changed to NO. if yes, please update accordingly.' (Site from DM).             | (b) (4), (b) (6)    | 30 Sep 2020 14:00:37 |
| Query 'Per DM CLR: Prophylaxis=YES. However, there is corresponding MH condition that matches this con med and is within the time frame. Please review and verify if this can be changed to NO. if yes, please update accordingly.' answered with 'updated' (Site from DM). | Afifah Ayub (b) (4) | 21 Sep 2020 14:59:51 |
| User opened query 'Per DM CLR: Prophylaxis=YES. However, there is corresponding MH condition that matches this con med and is within the time frame. Please review and verify if this can be changed to NO. if yes, please update accordingly.' (Site from DM).             | (b) (4), (b) (6)    | 18 Sep 2020 09:28:09 |
| User entered 'Yes (Y)'  | (b) (4), (b) (6)    | 03 Aug 2020 21:15:13 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Indication](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 14 Oct 2020 15:52:03 |
| User entered 'Iron Deficiency' | (b) (4), (b) (6) | 03 Aug 2020 21:15:13 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:52:08 |
| User entered '65'   | (b) (4), (b) (6) | 03 Aug 2020 21:15:13 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:15

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 15:52:11 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 03 Aug 2020 21:15:13 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:46:15**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:52:15 |
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 21:15:13 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:15

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 14 Oct 2020 15:55:26 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 03 Aug 2020 21:15:13 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:15

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:55:29 |
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 21:15:13 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 14 Oct 2020 15:56:07 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 03 Aug 2020 21:15:13 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:46:15**

[If route of administration is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:56:08 |
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 21:15:13 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:46:15

Start date (dd MMM yyyy)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 15:56:12 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).    | (b) (4), (b) (6) | 03 Aug 2020 23:35:52 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System           | 03 Aug 2020 21:21:20 |
| User entered 'UN UNK 2018'   | (b) (4), (b) (6) | 03 Aug 2020 21:15:13 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:56:14 |
| User entered '0'    | (b) (4), (b) (6) | 03 Aug 2020 21:15:13 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Ongoing?](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| DataPoint Un-verified.                                   | Reagan Reed (b) (4) | 27 Oct 2020 17:42:54 |
|  | (b) (4)             |                      |
| User entered 'No (N)' reason for change: New Information | Reagan Reed (b) (4) | 27 Oct 2020 17:42:54 |
|  | (b) (4)             |                      |
| DataPoint Verified.                                      | (b) (4), (b) (6)    | 14 Oct 2020 15:56:16 |
|  | (b) (4), (b) (6)    |                      |
| User entered 'Yes (Y)'                                   | (b) (4), (b) (6)    | 03 Aug 2020 21:15:13 |
|  |                     |                      |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:46:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| DataPoint Un-verified.                        | Reagan Reed (b) (4) | 27 Oct 2020 17:42:54 |
|   | (b) (4)             |                      |
| User entered 'UN Aug 2020' reason for change: | Reagan Reed (b) (4) | 27 Oct 2020 17:42:54 |
| Data Entry Error                              | (b) (4)             |                      |
| DataPoint Verified.                           | (b) (4), (b) (6)    | 14 Oct 2020 15:56:17 |
|   |                     |                      |
| User entered empty.                           | (b) (4), (b) (6)    | 03 Aug 2020 21:15:13 |
|   |                     |                      |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 15:56:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:15:13 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Aug 2020 21:15:13 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 03 Aug 2020 21:15:13 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Aug 2020 21:15:13 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:15

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                | 14 Oct 2020 15:58:33 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 03 Aug 2020 22:40:12 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4) | 03 Aug 2020 22:40:12 |
| Data point term sent to Coder  | System                          | 03 Aug 2020 21:17:26 |
| User entered 'Cetirizine ( Zyrtec )'   | (b) (4), (b) (6)                | 03 Aug 2020 21:16:38 |



US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:15

[Prophylaxis](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User closed query 'Per source, the answer in no. Please verify and update accordingly.' (Site from CRA).             | (b) (4), (b) (6)    | 23 Oct 2020 14:41:01 |
| DataPoint Verified.  | (b) (4), (b) (6)    | 23 Oct 2020 14:40:59 |
| Query 'Per source, the answer in no. Please verify and update accordingly.' answered with 'updated' (Site from CRA). | Afifah Ayub (b) (4) | 14 Oct 2020 17:03:41 |
| User entered 'No (N)' reason for change: Data Entry Error  | Afifah Ayub (b) (4) | 14 Oct 2020 17:03:36 |
| User opened query 'Per source, the answer in no. Please verify and update accordingly.' (Site from CRA).             | (b) (4), (b) (6)    | 14 Oct 2020 16:00:06 |
| User entered 'Yes (Y)'   | (b) (4), (b) (6)    | 03 Aug 2020 21:16:38 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Indication](#)

| Audit                             | User             | Time (GMT)           |
|-----------------------------------|------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6) | 14 Oct 2020 16:00:11 |
| User entered 'Seasonal Allergies' | (b) (4), (b) (6) | 03 Aug 2020 21:16:38 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:15

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:00:15 |
| User entered '10'   | (b) (4), (b) (6) | 03 Aug 2020 21:16:38 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:15

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 16:00:16 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 03 Aug 2020 21:16:38 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:46:15**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:00:18 |
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 21:16:38 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 14 Oct 2020 16:00:20 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 03 Aug 2020 21:16:38 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:46:15**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:00:23 |
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 21:16:38 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 14 Oct 2020 16:00:27 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 03 Aug 2020 21:16:38 |



US3212013

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:46:15**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:00:29 |
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 21:16:38 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:46:15

Start date (dd MMM yyyy)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 16:00:30 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).    | (b) (4), (b) (6) | 03 Aug 2020 23:35:56 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System           | 03 Aug 2020 21:21:20 |
| User entered 'UN UNK 2010'   | (b) (4), (b) (6) | 03 Aug 2020 21:16:38 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:00:33 |
| User entered '0'    | (b) (4), (b) (6) | 03 Aug 2020 21:16:38 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 16:00:35 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 03 Aug 2020 21:16:38 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:46:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 16:00:37 |
| User entered empty. | (b) (4), (b) (6) | 03 Aug 2020 21:16:38 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 16:00:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Aug 2020 21:16:38 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 03 Aug 2020 21:16:38 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 03 Aug 2020 21:16:38 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 03 Aug 2020 21:16:38 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:15

[Name of Medication](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 14 Oct 2020 16:00:52 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: MEDROXYPROGESTERONE ACETATE, PRODUCTSYNONYM: PROVERA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 17 Sep 2020 08:17:50 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)  | 17 Sep 2020 08:17:50 |
| Data point term sent to Coder   | System                           | 14 Sep 2020 16:15:37 |
| User entered 'Provera'  | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:15:18 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Prophylaxis](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 14 Oct 2020 16:00:55 |
| User entered 'No (N)' | Laura Ngansop Djampou | 14 Sep 2020 16:15:18 |
|                       | (b) (4)               |                      |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Indication](#)

| Audit                           | User                  | Time (GMT)           |
|---------------------------------|-----------------------|----------------------|
| DataPoint Verified.             | (b) (4), (b) (6)      | 14 Oct 2020 16:00:57 |
| User entered 'Uterine bleeding' | Laura Ngansop Djampou | 14 Sep 2020 16:15:18 |
|                                 | (b) (4)               |                      |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:46:15

[Dose per administration](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.<br>' (Site from DM).             | (b) (4), (b) (6)                 | 03 Nov 2020 14:54:00 |
| Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.<br>' answered with 'updated' (Site from DM). | Anna Pena (b) (4)<br>(b) (4)     | 19 Oct 2020 16:19:11 |
| DataPoint Un-verified.   | Anna Pena (b) (4)<br>(b) (4)     | 19 Oct 2020 16:19:02 |
| User entered '10' reason for change: Data Entry Error  | Anna Pena (b) (4)<br>(b) (4)     | 19 Oct 2020 16:19:02 |
| DataPoint Verified.  | (b) (4), (b) (6)                 | 14 Oct 2020 16:03:44 |
| User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.<br>' (Site from DM).             | (b) (4), (b) (6)                 | 14 Oct 2020 09:40:28 |
| User entered 'I'   | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:15:18 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose unit](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 14 Oct 2020 16:03:46 |
| User entered 'mg (mg)' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:15:18 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:46:15**

[If dose unit is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 16:03:51 |
| User entered empty. | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:15:18 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Frequency](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)      | 14 Oct 2020 16:03:53 |
| User entered 'twice daily (BID)' | Laura Ngansop Djampou | 14 Sep 2020 16:15:18 |
|                                  | (b) (4)               |                      |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:46:15**

[If frequency is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 14 Oct 2020 16:03:57 |
| User entered empty. | Laura Ngansop Djampou | 14 Sep 2020 16:15:18 |
|                     | (b) (4)               |                      |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Route of administration](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 14 Oct 2020 16:03:59 |
| User entered 'Oral (ORAL)' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:15:18 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:46:15**

[If route of administration is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 14 Oct 2020 16:11:10 |
| User entered empty. | Laura Ngansop Djampou | 14 Sep 2020 16:15:18 |
|                     | (b) (4)               |                      |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 14 Oct 2020 16:11:12 |
| User entered '28 Aug 2020' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:15:18 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 16:11:15 |
| User entered '0'    | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:15:18 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Ongoing?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 14 Oct 2020 16:11:17 |
| User entered 'No (N)' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:15:18 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:46:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 14 Oct 2020 16:11:20 |
| User entered '29 Aug 2020' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:15:18 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this medication taken for solicited event?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 14 Oct 2020 16:11:23 |
| User entered 'No (N)' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:15:18 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 14 Sep 2020 16:15:18 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 14 Sep 2020 16:15:18 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 14 Sep 2020 16:15:18 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:15

[Name of Medication](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 14 Oct 2020 16:11:36 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORGESTIMATE, PRODUCTSYNONYM: SPRINTEC - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 16 Sep 2020 15:41:38 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)  | 16 Sep 2020 15:41:38 |
| Data point term sent to Coder   | System                           | 14 Sep 2020 16:17:44 |
| User entered 'Sprintec (norgestimate/ethinyl estradiol)'  | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:17:03 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Prophylaxis](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 14 Oct 2020 16:11:37 |
| User entered 'No (N)' | Laura Ngansop Djampou | 14 Sep 2020 16:17:03 |
|                       | (b) (4)               |                      |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Indication](#)

| Audit                           | User                  | Time (GMT)           |
|---------------------------------|-----------------------|----------------------|
| DataPoint Verified.             | (b) (4), (b) (6)      | 14 Oct 2020 16:11:46 |
| User entered 'Uterine bleeding' | Laura Ngansop Djampou | 14 Sep 2020 16:17:03 |
|                                 | (b) (4)               |                      |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose per administration](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                 | 14 Oct 2020 16:11:52 |
| User entered '0.25/0.035' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:17:03 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose unit](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 14 Oct 2020 16:11:54 |
| User entered 'mg (mg)' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:17:03 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:46:15**

If dose unit is Other, specify

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 14 Oct 2020 16:11:56 |
| User entered empty. | Laura Ngansop Djampou | 14 Sep 2020 16:17:03 |
|                     | (b) (4)               |                      |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Frequency](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)      | 14 Oct 2020 16:11:57 |
| User entered 'other (OTHER)' | Laura Ngansop Djampou | 14 Sep 2020 16:17:03 |
|                              | (b) (4)               |                      |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:15

If frequency is Other, specify

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 14 Oct 2020 16:12:00 |
| User entered 'Take 1 every 6 hours x 4 days, then take 1 every 8 hrs x 3 days, then take 1 every 12 hrs x 2 days, then take 1 daily' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:17:03 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Route of administration](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 14 Oct 2020 16:12:02 |
| User entered 'Oral (ORAL)' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:17:03 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:46:15**

If route of administration is Other, specify

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 14 Oct 2020 16:12:04 |
| User entered empty. | Laura Ngansop Djampou | 14 Sep 2020 16:17:03 |
|                     | (b) (4)               |                      |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 14 Oct 2020 16:12:08 |
| User entered '29 Aug 2020' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:17:03 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 16:12:14 |
| User entered '0'    | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:17:03 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:15

[Ongoing?](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.<br>' (Site from DM).             | (b) (4), (b) (6)                 | 22 Oct 2020 03:50:30 |
| DataPoint Verified.   | (b) (4), (b) (6)                 | 14 Oct 2020 16:12:12 |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.<br>' answered with 'updated' (Site from DM). | Afifah Ayub (b) (4)<br>(b) (4)   | 05 Oct 2020 16:13:42 |
| User entered 'No (N)' reason for change: Per Query Resolution   | Afifah Ayub (b) (4)<br>(b) (4)   | 05 Oct 2020 16:13:37 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.<br>' (Site from DM).             | (b) (4), (b) (6)                 | 05 Oct 2020 07:43:22 |
| User entered 'Yes (Y)'  | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:17:03 |



US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:46:15

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)              | 14 Oct 2020 16:12:16 |
| User entered '04 Sep 2020' reason for change: Per Query Resolution | Afifah Ayub (b) (4)           | 05 Oct 2020 16:13:37 |
| User entered empty.  | Laura Ngansop Djampou (b) (4) | 14 Sep 2020 16:17:03 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this medication taken for solicited event?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 14 Oct 2020 16:12:18 |
| User entered 'No (N)' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:17:03 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 14 Sep 2020 16:17:03 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 14 Sep 2020 16:17:03 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 14 Sep 2020 16:17:03 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:15

Name of Medication

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening IRON DEFICIENCY should be recorded, and update con med indication or provide clarification. ' (Site from DM).                        | (b) (4), (b) (6)               | 03 Nov 2020 14:59:07 |
| User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #3. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).   | (b) (4), (b) (6)               | 03 Nov 2020 14:57:06 |
| Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening IRON DEFICIENCY should be recorded, and update con med indication or provide clarification. ' answered with 'updated per source' (Site from DM). | Reagan Reed (b) (4)<br>(b) (4) | 27 Oct 2020 17:43:33 |
| Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #3. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'updated per source' (Site from DM).  | Reagan Reed (b) (4)<br>(b) (4) | 27 Oct 2020 17:43:17 |
| DataPoint Verified.  | (b) (4), (b) (6)               | 14 Oct 2020 16:15:54 |
| User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #3. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).   | (b) (4), (b) (6)               | 14 Oct 2020 09:40:14 |
| User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening IRON DEFICIENCY should be recorded, and update con med indication or provide clarification. ' (Site from DM).                        | (b) (4), (b) (6)               | 14 Oct 2020 09:40:08 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:46:15

[Name of Medication](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE, PRODUCTSYNONYM: FERROUS SULPHATE [FERROUS SULFATE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 15 Sep 2020 10:11:45 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)  | 15 Sep 2020 10:11:45 |
| Data point term sent to Coder  | System                           | 14 Sep 2020 16:22:51 |
| User entered 'Ferrous Sulphate'  | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:22:05 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Prophylaxis](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 14 Oct 2020 16:15:56 |
| User entered 'No (N)' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:22:05 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Indication](#)

| Audit                               | User                             | Time (GMT)           |
|-------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                 | (b) (4), (b) (6)                 | 14 Oct 2020 16:15:58 |
| User entered 'Fe Deficiency anemia' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:22:05 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose per administration](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 16:16:00 |
| User entered '325'  | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:22:05 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose unit](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 14 Oct 2020 16:16:02 |
| User entered 'mg (mg)' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:22:05 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:46:15**

[If dose unit is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 14 Oct 2020 16:16:10 |
| User entered empty. | Laura Ngansop Djampou | 14 Sep 2020 16:22:05 |
|                     | (b) (4)               |                      |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Frequency](#)

| Audit                                  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6)                 | 14 Oct 2020 16:16:12 |
| User entered 'three times daily (TID)' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:22:05 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:46:15**

[If frequency is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 14 Oct 2020 16:16:13 |
| User entered empty. | Laura Ngansop Djampou | 14 Sep 2020 16:22:05 |
|                     | (b) (4)               |                      |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Route of administration](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 14 Oct 2020 16:16:15 |
| User entered 'Oral (ORAL)' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:22:05 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:46:15**

[If route of administration is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 16:16:17 |
| User entered empty. | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:22:05 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 14 Oct 2020 16:16:20 |
| User entered '27 Aug 2020' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:22:05 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 16:16:22 |
| User entered '0'    | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:22:05 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Ongoing?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 14 Oct 2020 16:16:23 |
| User entered 'Yes (Y)' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:22:05 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:46:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 14 Oct 2020 16:16:25 |
| User entered empty. | Laura Ngansop Djampou | 14 Sep 2020 16:22:05 |
|                     | (b) (4)               |                      |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this medication taken for solicited event?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 14 Oct 2020 16:16:26 |
| User entered 'No (N)' | Laura Ngansop Djampou<br>(b) (4) | 14 Sep 2020 16:22:05 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 14 Sep 2020 16:22:05 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 14 Sep 2020 16:22:05 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 14 Sep 2020 16:22:05 |



US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:15

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                | 14 Oct 2020 16:16:33 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: IBUPROFEN,<br>PRODUCTSYNONYM: MOTRIN [IBUPROFEN] -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 30 Sep 2020 00:00:38 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4) | 30 Sep 2020 00:00:38 |
| Data point term sent to Coder   | System                          | 29 Sep 2020 21:52:42 |
| User entered 'Motrin'   | Afifah Ayub (b) (4)<br>(b) (4)  | 29 Sep 2020 21:52:01 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 14 Oct 2020 16:16:38 |
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:01 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Indication](#)

| Audit                             | User                           | Time (GMT)           |
|-----------------------------------|--------------------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)               | 14 Oct 2020 16:29:01 |
| User entered 'postoperative pain' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:01 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose per administration](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:29:04 |
| User entered '800'  | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:01 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:15

[Dose unit](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 14 Oct 2020 16:29:06 |
| User entered 'mg (mg)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:01 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:46:15**

[If dose unit is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:29:09 |
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:01 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Frequency](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)               | 14 Oct 2020 16:29:11 |
| User entered 'as needed (PRN)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:01 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:46:15**

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:29:13 |
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:01 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 14 Oct 2020 16:29:15 |
| User entered 'Oral (ORAL)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:01 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:46:15**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:29:17 |
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:01 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 14 Oct 2020 16:29:19 |
| User entered '23 Sep 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:01 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:29:22 |
| User entered '0'    | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:01 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:15

[Ongoing?](#)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| DataPoint Un-verified.                                    | Afifah Ayub (b) (4) | 26 Oct 2020 21:00:39 |
|   | (b) (4)             |                      |
| User entered 'No (N)' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 26 Oct 2020 21:00:39 |
|   | (b) (4)             |                      |
| DataPoint Verified.                                       | (b) (4), (b) (6)    | 14 Oct 2020 16:29:24 |
|   |                     |                      |
| User entered 'Yes (Y)'                                    | Afifah Ayub (b) (4) | 29 Sep 2020 21:52:01 |
|   | (b) (4)             |                      |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:46:15

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| DataPoint Un-verified.   | Afifah Ayub (b) (4) | 26 Oct 2020 21:00:39 |
|  | (b) (4)             |                      |
| User entered '07 Oct 2020' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 26 Oct 2020 21:00:39 |
|  | (b) (4)             |                      |
| DataPoint Verified.  | (b) (4), (b) (6)    | 14 Oct 2020 16:29:26 |
|  |                     |                      |
| User entered empty.  | Afifah Ayub (b) (4) | 29 Sep 2020 21:52:01 |
|  | (b) (4)             |                      |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 14 Oct 2020 16:29:29 |
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:01 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Sep 2020 21:52:01 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Sep 2020 21:52:01 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Sep 2020 21:52:01 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:15

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                | 14 Oct 2020 16:30:04 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 29 Sep 2020 23:05:41 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4) | 29 Sep 2020 23:05:41 |
| Data point term sent to Coder  | System                          | 29 Sep 2020 21:53:44 |
| User entered 'Colace'  | Afifah Ayub (b) (4)<br>(b) (4)  | 29 Sep 2020 21:52:44 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Prophylaxis](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 14 Oct 2020 16:30:07 |
| User entered 'Yes (Y)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:44 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:15

[Indication](#)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 14 Oct 2020 16:30:10 |
| User entered 'prevention of constipation with postoperative opioid use; Hysterectomy' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:44 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose per administration](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:30:12 |
| User entered '100'  | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:44 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:15

[Dose unit](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 14 Oct 2020 16:30:15 |
| User entered 'mg (mg)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:44 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:46:15**

[If dose unit is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:30:17 |
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:44 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Frequency](#)

| Audit                            | User                           | Time (GMT)           |
|----------------------------------|--------------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)               | 14 Oct 2020 16:30:19 |
| User entered 'twice daily (BID)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:44 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:46:15**

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:30:21 |
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:44 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 14 Oct 2020 16:30:23 |
| User entered 'Oral (ORAL)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:44 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:46:15**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:30:26 |
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:44 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 14 Oct 2020 16:30:28 |
| User entered '23 Sep 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:44 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:30:30 |
| User entered '0'    | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:44 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Ongoing?](#)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| DataPoint Un-verified.                                    | Afifah Ayub (b) (4) | 26 Oct 2020 21:17:50 |
|   | (b) (4)             |                      |
| User entered 'No (N)' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 26 Oct 2020 21:17:50 |
|   | (b) (4)             |                      |
| DataPoint Verified.                                       | (b) (4), (b) (6)    | 14 Oct 2020 16:30:33 |
|   |                     |                      |
| User entered 'Yes (Y)'                                    | Afifah Ayub (b) (4) | 29 Sep 2020 21:52:44 |
|   | (b) (4)             |                      |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:46:15

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| DataPoint Un-verified.   | Afifah Ayub (b) (4) | 26 Oct 2020 21:17:50 |
|  | (b) (4)             |                      |
| User entered '07 Oct 2020' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 26 Oct 2020 21:17:50 |
|  | (b) (4)             |                      |
| DataPoint Verified.  | (b) (4), (b) (6)    | 14 Oct 2020 16:30:37 |
|  |                     |                      |
| User entered empty.  | Afifah Ayub (b) (4) | 29 Sep 2020 21:52:44 |
|  | (b) (4)             |                      |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 14 Oct 2020 16:30:39 |
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:52:44 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 29 Sep 2020 21:52:44 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Sep 2020 21:52:44 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 29 Sep 2020 21:52:44 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:46:15

[Name of Medication](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)     | 14 Oct 2020 16:30:51 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 29 Sep 2020 21:54:39 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | (b) (4)              | 29 Sep 2020 21:54:39 |
| Data point term sent to Coder  | System               | 29 Sep 2020 21:53:45 |
| User entered 'Acetaminophen'   | Afifah Ayub (b) (4)  | 29 Sep 2020 21:53:14 |
|  | (b) (4)              |                      |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:46:15**

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 14 Oct 2020 16:30:53 |
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:14 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:46:15**

[Indication](#)

| Audit                             | User                           | Time (GMT)           |
|-----------------------------------|--------------------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)               | 14 Oct 2020 16:30:58 |
| User entered 'postoperative pain' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:14 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose per administration](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:31:01 |
| User entered '325'  | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:14 |



US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:46:15

[Dose unit](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 14 Oct 2020 16:31:10 |
| User entered 'mg (mg)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:14 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:46:15**

[If dose unit is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:31:12 |
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:14 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:46:15**

[Frequency](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)               | 14 Oct 2020 16:31:15 |
| User entered 'as needed (PRN)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:14 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:46:15**

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:31:18 |
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:14 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:46:15**

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 14 Oct 2020 16:31:20 |
| User entered 'Oral (ORAL)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:14 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:46:15**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:31:22 |
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:14 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 14 Oct 2020 16:31:23 |
| User entered '23 Sep 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:14 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:31:25 |
| User entered '0'    | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:14 |



US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:46:15

[Ongoing?](#)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| DataPoint Un-verified.                                    | Afifah Ayub (b) (4) | 26 Oct 2020 21:18:15 |
|   | (b) (4)             |                      |
| User entered 'No (N)' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 26 Oct 2020 21:18:15 |
|   | (b) (4)             |                      |
| DataPoint Verified.                                       | (b) (4), (b) (6)    | 14 Oct 2020 16:31:28 |
|   |                     |                      |
| User entered 'Yes (Y)'                                    | Afifah Ayub (b) (4) | 29 Sep 2020 21:53:14 |
|   | (b) (4)             |                      |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:46:15

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| DataPoint Un-verified.   | Afifah Ayub (b) (4) | 26 Oct 2020 21:18:15 |
|  | (b) (4)             |                      |
| User entered '07 Oct 2020' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 26 Oct 2020 21:18:15 |
|  | (b) (4)             |                      |
| DataPoint Verified.  | (b) (4), (b) (6)    | 14 Oct 2020 16:31:29 |
|  |                     |                      |
| User entered empty.  | Afifah Ayub (b) (4) | 29 Sep 2020 21:53:14 |
|  | (b) (4)             |                      |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 14 Oct 2020 16:31:32 |
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:14 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:46:15**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Sep 2020 21:53:14 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Sep 2020 21:53:14 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Sep 2020 21:53:14 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:46:15

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                | 14 Oct 2020 16:31:52 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 02 Oct 2020 21:51:55 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4) | 02 Oct 2020 21:51:55 |
| Data point term sent to Coder  | System                          | 29 Sep 2020 21:54:46 |
| User entered 'Norco (hydrocodone/acetaminophen)'   | Afifah Ayub (b) (4)<br>(b) (4)  | 29 Sep 2020 21:53:46 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:46:15**

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 14 Oct 2020 16:31:54 |
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:46 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:46:15**

[Indication](#)

| Audit                             | User                           | Time (GMT)           |
|-----------------------------------|--------------------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)               | 14 Oct 2020 16:31:56 |
| User entered 'postoperative pain' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:46 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose per administration](#)

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)               | 14 Oct 2020 16:32:01 |
| User entered '5/325' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:46 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:46:15

[Dose unit](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 14 Oct 2020 16:32:03 |
| User entered 'mg (mg)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:46 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:46:15**

[If dose unit is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:32:06 |
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:46 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:46:15**

[Frequency](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)               | 14 Oct 2020 16:32:08 |
| User entered 'as needed (PRN)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:46 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:46:15**

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:32:09 |
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:46 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:46:15**

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 14 Oct 2020 16:32:11 |
| User entered 'Oral (ORAL)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:46 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:46:15**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:32:12 |
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:46 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 14 Oct 2020 16:32:15 |
| User entered '22 Sep 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:46 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:32:16 |
| User entered '0'    | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:46 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:46:15

[Ongoing?](#)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| DataPoint Un-verified.                                    | Afifah Ayub (b) (4) | 26 Oct 2020 21:18:47 |
|   | (b) (4)             |                      |
| User entered 'No (N)' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 26 Oct 2020 21:18:47 |
|   | (b) (4)             |                      |
| DataPoint Verified.                                       | (b) (4), (b) (6)    | 14 Oct 2020 16:32:19 |
|   |                     |                      |
| User entered 'Yes (Y)'                                    | Afifah Ayub (b) (4) | 29 Sep 2020 21:53:46 |
|   | (b) (4)             |                      |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:46:15

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| DataPoint Un-verified.   | Afifah Ayub (b) (4) | 26 Oct 2020 21:18:47 |
|  | (b) (4)             |                      |
| User entered '07 Oct 2020' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 26 Oct 2020 21:18:47 |
|  | (b) (4)             |                      |
| DataPoint Verified.  | (b) (4), (b) (6)    | 14 Oct 2020 16:32:21 |
|  |                     |                      |
| User entered empty.  | Afifah Ayub (b) (4) | 29 Sep 2020 21:53:46 |
|  | (b) (4)             |                      |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 14 Oct 2020 16:32:23 |
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:53:46 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:46:15**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Sep 2020 21:53:46 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Sep 2020 21:53:46 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Sep 2020 21:53:46 |



US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:46:15

[Name of Medication](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)     | 14 Oct 2020 16:32:33 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;LEVONORGESTREL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 04 Oct 2020 08:15:39 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | (b) (4)              | 04 Oct 2020 08:15:39 |
| Data point term sent to Coder   | System               | 29 Sep 2020 21:54:48 |
| User entered 'Levonorgestrel/ethinyl estradiol'   | Afifah Ayub (b) (4)  | 29 Sep 2020 21:54:30 |
|   | (b) (4)              |                      |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:46:15**

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 14 Oct 2020 16:32:36 |
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:54:30 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:46:15**

[Indication](#)

| Audit                           | User                           | Time (GMT)           |
|---------------------------------|--------------------------------|----------------------|
| DataPoint Verified.             | (b) (4), (b) (6)               | 14 Oct 2020 16:32:41 |
| User entered 'Uterine bleeding' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:54:30 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:46:15

[Dose per administration](#)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| DataPoint Un-verified.                                      | Afifah Ayub (b) (4) | 26 Oct 2020 20:48:16 |
|   | (b) (4)             |                      |
| User entered '0.1/0.02' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 26 Oct 2020 20:48:16 |
|   | (b) (4)             |                      |
| DataPoint Verified.   | (b) (4), (b) (6)    | 14 Oct 2020 16:36:45 |
|   |                     |                      |
| User entered 'UNK'  | Afifah Ayub (b) (4) | 29 Sep 2020 21:54:30 |
|   | (b) (4)             |                      |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:46:15

[Dose unit](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 14 Oct 2020 16:36:47 |
| User entered 'mg (mg)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:54:30 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:46:15**

[If dose unit is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:36:49 |
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:54:30 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:46:15**

[Frequency](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)               | 14 Oct 2020 16:36:51 |
| User entered 'once daily (QD)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:54:30 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:46:15**

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:36:53 |
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:54:30 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:46:15**

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 14 Oct 2020 16:36:54 |
| User entered 'Oral (ORAL)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:54:30 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:46:15**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:37:00 |
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:54:30 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 14 Oct 2020 16:37:02 |
| User entered '05 Sep 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:54:30 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 14 Oct 2020 16:37:03 |
| User entered '0'    | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:54:30 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:46:15

[Ongoing?](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)    | 14 Oct 2020 16:37:09 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 29 Sep 2020 21:54:35 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 29 Sep 2020 21:54:35 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Afifah Ayub (b) (4) | 29 Sep 2020 21:54:35 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 29 Sep 2020 21:54:30 |
| User entered empty.  | Afifah Ayub (b) (4) | 29 Sep 2020 21:54:30 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:46:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 14 Oct 2020 16:37:11 |
| User entered '21 Sep 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:54:30 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 14 Oct 2020 16:37:14 |
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:54:30 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:46:15**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Sep 2020 21:54:30 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Sep 2020 21:54:30 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 29 Sep 2020 21:54:30 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:46:15

Name of Medication

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANATE POTASSIUM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 17 Oct 2020 09:43:38 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4) | 17 Oct 2020 09:43:38 |
| Data point term sent to Coder   | System                          | 16 Oct 2020 20:47:45 |
| User entered 'Amoxicillin Clavulanate'  | Afifah Ayub (b) (4)<br>(b) (4)  | 16 Oct 2020 20:47:30 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:46:15

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 20:47:30 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:46:15

[Indication](#)

| Audit                                  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered 'urinary tract infection' | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 20:47:30 |

US3212013

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose per administration](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered '500/125' | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 20:47:30 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:46:15

[Dose unit](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'mg (mg)' | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 20:47:30 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:46:15

If dose unit is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 20:47:30 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:46:15**

[Frequency](#)

| Audit                            | User                           | Time (GMT)           |
|----------------------------------|--------------------------------|----------------------|
| User entered 'twice daily (BID)' | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 20:47:30 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:46:15

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 20:47:30 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:46:15

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 20:47:30 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:46:15**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 20:47:30 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:46:15

Start date (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '12 Oct 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 20:47:30 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 20:47:30 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:46:15**

[Ongoing?](#)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 26 Oct 2020 21:19:52 |
| User entered 'Yes (Y)'                                    | Afifah Ayub (b) (4) | 16 Oct 2020 20:47:30 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:46:15**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User entered '19 Oct 2020' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 26 Oct 2020 21:19:52 |
| User entered empty.  | Afifah Ayub (b) (4) | 16 Oct 2020 20:47:30 |



US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:46:15

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 16 Oct 2020 20:47:30 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:46:15**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 16 Oct 2020 20:47:30 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 16 Oct 2020 20:47:30 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 16 Oct 2020 20:47:30 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:46:15

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 26 Oct 2020 21:17:39 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4) | 26 Oct 2020 21:17:39 |
| Data point term sent to Coder  | System                          | 26 Oct 2020 21:16:54 |
| User entered 'fexofenadine'  | Afifah Ayub (b) (4)<br>(b) (4)  | 26 Oct 2020 21:16:53 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:46:15

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 21:16:53 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:46:15

[Indication](#)

| Audit                             | User                           | Time (GMT)           |
|-----------------------------------|--------------------------------|----------------------|
| User entered 'seasonal allergies' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 21:16:53 |

US3212013

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose per administration](#)

| Audit              | User                           | Time (GMT)           |
|--------------------|--------------------------------|----------------------|
| User entered '180' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 21:16:53 |



US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:46:15

[Dose unit](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'mg (mg)' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 21:16:53 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:46:15

If dose unit is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 21:16:53 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:46:15**

[Frequency](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| User entered 'as needed (PRN)' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 21:16:53 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:46:15**

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 21:16:53 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:46:15

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 21:16:53 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:46:15**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 21:16:53 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'UN UNK 2010' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 21:16:53 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 21:16:53 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:46:15**

[Ongoing?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 21:16:53 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:46:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 21:16:53 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:46:15

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 26 Oct 2020 21:16:53 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:46:15**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 21:16:53 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 21:16:53 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 21:16:53 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:46:15

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 29 Oct 2020 21:05:20 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4) | 29 Oct 2020 21:05:20 |
| Data point term sent to Coder   | System                          | 28 Oct 2020 20:34:45 |
| User entered 'Prednisone'   | Afifah Ayub (b) (4)<br>(b) (4)  | 28 Oct 2020 20:34:12 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:46:15

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:12 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:46:15**

[Indication](#)

| Audit                    | User                           | Time (GMT)           |
|--------------------------|--------------------------------|----------------------|
| User entered 'foot pain' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:12 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:46:15

[Dose per administration](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '4' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:12 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:46:15

[Dose unit](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'mg (mg)' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:12 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:46:15**

If dose unit is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:12 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:46:15

[Frequency](#)

| Audit                        | User                           | Time (GMT)           |
|------------------------------|--------------------------------|----------------------|
| User entered 'other (OTHER)' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:12 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:46:15

[If frequency is Other, specify](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered 'Tapered dose: 6 today, 5 tomorrow, 4 on 30Oct, 3 on 31Oct, 2 on 1Nov, 1 on 2Nov' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:12 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:46:15

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:12 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:46:15

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:12 |



US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:46:15

Start date (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '28 Oct 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:12 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:12 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:46:15**

[Ongoing?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:12 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:46:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:12 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:46:15

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:12 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:46:15**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 20:34:12 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 20:34:12 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 20:34:12 |



US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:46:15

Name of Medication

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| User closed query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. (7 days after dose 2). (Site from DM).                             | (b) (4), (b) (6)    | 18 Nov 2020 17:29:59 |
| Query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. (7 days after dose 2). answered with 'deviation already noted' (Site from DM). | Reagan Reed (b) (4) | 12 Nov 2020 19:19:22 |
| User opened query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. (7 days after dose 2). (Site from DM).                             | (b) (4), (b) (6)    | 12 Nov 2020 19:18:59 |
| User closed query 'Per MM, please confirm if the subject did not meet EC#12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening). If met, please report as possible protocol deviation. (Site from DM).  | (b) (4), (b) (6)    | 12 Nov 2020 19:18:24 |
| Query 'Per MM, please confirm if the subject did not meet EC#12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening). If met, please report as possible protocol deviation. answered with 'protocol deviation noted in progress note captured on 04NOV2020' (Site from DM).  | Reagan Reed (b) (4) | 12 Nov 2020 18:42:29 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:46:15

[Name of Medication](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User opened query 'Per MM, please confirm if the subject did not meet EC#12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening). If met, please report as possible protocol deviation.' (Site from DM). | (b) (4), (b) (6)     | 12 Nov 2020 18:24:53 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4) | 29 Oct 2020 20:06:37 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | (b) (4)              |                      |
| Data point term sent to Coder   | System               | 28 Oct 2020 20:35:46 |
| User entered 'Influenza vaccination'  | Afifah Ayub (b) (4)  | 28 Oct 2020 20:34:48 |
|   | (b) (4)              |                      |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:46:15**

[Prophylaxis](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User entered 'Yes (Y)' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 04 Nov 2020 18:05:37 |
| User entered 'No (N)'                                      | Afifah Ayub (b) (4) | 28 Oct 2020 20:34:48 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:46:15**

[Indication](#)

| Audit                       | User                           | Time (GMT)           |
|-----------------------------|--------------------------------|----------------------|
| User entered 'immunization' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:48 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:46:15

[Dose per administration](#)

| Audit              | User                           | Time (GMT)           |
|--------------------|--------------------------------|----------------------|
| User entered '0.5' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:48 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:46:15

[Dose unit](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'mL (mL)' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:48 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:46:15

If dose unit is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:48 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:46:15

[Frequency](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'once (ONCE)' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:48 |



US3212013

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:46:15**

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:48 |

US3212013

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:46:15**

[Route of administration](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User entered 'Intramuscular (INTRAMUSCULAR)' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:48 |

US3212013

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:46:15**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:48 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:46:15

Start date (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '14 Oct 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:48 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:46:15

Start date completely unknown

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:48 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:46:15**

[Ongoing?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:48 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:46:15

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '14 Oct 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:48 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:46:15

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Afifah Ayub (b) (4)<br>(b) (4) | 28 Oct 2020 20:34:48 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:46:15**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 20:34:48 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 20:34:48 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 20:34:48 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:46:15

[Name of Medication](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE, PRODUCTSYNONYM: DIFLUCAN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 04 Nov 2020 22:56:30 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)  | 04 Nov 2020 22:56:30 |
| Data point term sent to Coder   | System                           | 04 Nov 2020 21:37:22 |
| User entered 'Fluconazole (Diflucan)'   | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:37:09 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:46:15

[Prophylaxis](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:37:09 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:46:15**

[Indication](#)

| Audit                              | User                             | Time (GMT)           |
|------------------------------------|----------------------------------|----------------------|
| User entered 'vaginal candidiasis' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:37:09 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose per administration](#)

| Audit              | User                             | Time (GMT)           |
|--------------------|----------------------------------|----------------------|
| User entered '150' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:37:09 |

US3212013

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose unit](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'mg (mg)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:37:09 |



US3212013

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:46:15**

If dose unit is Other, specify

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:37:09 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:46:15**

[Frequency](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered 'once (ONCE)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:37:09 |

US3212013

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:46:15**

[If frequency is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:37:09 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:46:15**

[Route of administration](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:37:09 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:46:15**

If route of administration is Other, specify

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:37:09 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '20 Oct 2020' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:37:09 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:37:09 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:46:15**

[Ongoing?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:37:09 |



US3212013

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:46:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '20 Oct 2020' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:37:09 |

US3212013

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this medication taken for solicited event?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:37:09 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:46:15**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Nov 2020 21:37:09 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Nov 2020 21:37:09 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Nov 2020 21:37:09 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:46:15

[Name of Medication](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS, ATC: ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS, ATC: ANTIBIOTICS, PRODUCT: NYSTATIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 05 Nov 2020 05:03:37 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)  | 05 Nov 2020 05:03:37 |
| Data point term sent to Coder   | System                           | 04 Nov 2020 21:38:23 |
| User entered 'Nystatin'   | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:38:00 |

US3212013

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:46:15**

[Prophylaxis](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:38:00 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:46:15

[Indication](#)

| Audit                              | User                             | Time (GMT)           |
|------------------------------------|----------------------------------|----------------------|
| User entered 'vaginal candidiasis' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:38:00 |



US3212013

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose per administration](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '1' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:38:00 |

US3212013

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:46:15**

[Dose unit](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| User entered 'Other (OTHER)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:38:00 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:46:15

If dose unit is Other, specify

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System). | System                        | 05 Nov 2020 14:29:28 |
| User entered 'application' reason for change: Data Entry Error   | Reagan Reed (b) (4)           | 05 Nov 2020 14:29:28 |
| User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System). | System                        | 04 Nov 2020 21:38:00 |
| User entered empty.  | Laura Ngansop Djampou (b) (4) | 04 Nov 2020 21:38:00 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:46:15

[Frequency](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| User entered 'as needed (PRN)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:38:00 |

US3212013

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:46:15**

[If frequency is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:38:00 |

US3212013

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:46:15**

[Route of administration](#)

| Audit                            | User                             | Time (GMT)           |
|----------------------------------|----------------------------------|----------------------|
| User entered 'Topical (TOPICAL)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:38:00 |

US3212013

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:46:15**

If route of administration is Other, specify

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:38:00 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:46:15

Start date (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '28 Oct 2020' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:38:00 |



**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:46:15**

[Start date completely unknown](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:38:00 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:46:15**

[Ongoing?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:38:00 |

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:46:15

If not Ongoing, End date (*dd MMM yyyy*)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:38:00 |

US3212013

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:46:15**

[Was this medication taken for solicited event?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Laura Ngansop Djampou<br>(b) (4) | 04 Nov 2020 21:38:00 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:46:15**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Nov 2020 21:38:00 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Nov 2020 21:38:00 |

**US3212013**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:46:15**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Nov 2020 21:38:00 |

**US3212013**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 10:46:15**

[Were any concomitant procedures performed?](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)    | 14 Oct 2020 16:37:27 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 29 Sep 2020 21:36:33 |
| User entered 'No (N)'                                      | Afifah Ayub (b) (4) | 26 Aug 2020 18:16:40 |



**US3212013**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 10:46:15**

**Procedure/Surgery date** (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 14 Oct 2020 16:37:53 |
| User entered '27 Aug 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:37:10 |

**US3212013**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Procedure/Surgery](#)

| Audit                            | User                           | Time (GMT)           |
|----------------------------------|--------------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)               | 14 Oct 2020 16:37:56 |
| User entered 'Blood Transfusion' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:37:10 |

**US3212013****Folder: Concomitant Procedures (1)****Form: Concomitant Procedures (1)****Generated On: 26 Nov 2020 10:46:15****Indication**

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| User closed query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify..' (Site from DM).             | (b) (4), (b) (6)    | 18 Nov 2020 14:03:55 |
| Query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify..' answered with 'updated' (Site from DM). | Afifah Ayub (b) (4) | 02 Nov 2020 14:22:49 |
| User entered 'Adverse Event (AE)' reason for change: Data Entry Error   | (b) (4)             | 02 Nov 2020 14:22:42 |
| User opened query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify..' (Site from DM).             | (b) (4), (b) (6)    | 01 Nov 2020 04:32:57 |
| User closed query 'Per CDM: Please review the indication and update accordingly.' (Site from DM).   | (b) (4), (b) (6)    | 20 Oct 2020 07:08:00 |
| Query 'Per CDM: Please review the indication and update accordingly.' answered with 'updated' (Site from DM).   | Afifah Ayub (b) (4) | 15 Oct 2020 17:35:39 |
| DataPoint Un-verified.  | (b) (4)             | 15 Oct 2020 17:35:03 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error  | Afifah Ayub (b) (4) | 15 Oct 2020 17:35:03 |
| User opened query 'Per CDM: Please review the indication and update accordingly.' (Site from DM).   | (b) (4), (b) (6)    | 15 Oct 2020 15:34:09 |
| DataPoint Verified.   | (b) (4), (b) (6)    | 14 Oct 2020 16:37:57 |
| User entered 'Adverse Event (AE)'   | Afifah Ayub (b) (4) | 29 Sep 2020 21:37:10 |

US3212013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:46:15

If indication is Other, specify

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| User entered empty; reason for change Data Entry Error              | Afifah Ayub (b) (4) | 02 Nov 2020 14:22:42 |
| DataPoint Un-verified.  | (b) (4)             |                      |
|   | Afifah Ayub (b) (4) | 15 Oct 2020 17:35:03 |
|   | (b) (4)             |                      |
| User entered 'uterine bleeding' reason for change: Data Entry Error | Afifah Ayub (b) (4) | 15 Oct 2020 17:35:03 |
| DataPoint Verified.   | (b) (4)             |                      |
|   | (b) (4), (b) (6)    | 14 Oct 2020 16:37:59 |
|   |                     |                      |
| User entered empty.   | Afifah Ayub (b) (4) | 29 Sep 2020 21:37:10 |
|   | (b) (4)             |                      |

**US3212013**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 10:46:15**

**Procedure/Surgery date** (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 14 Oct 2020 16:38:09 |
| User entered '22 Sep 2020' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:37:29 |

**US3212013**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Procedure/Surgery](#)

| Audit                                | User                           | Time (GMT)           |
|--------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                  | (b) (4), (b) (6)               | 14 Oct 2020 16:38:11 |
| User entered 'Elective Hysterectomy' | Afifah Ayub (b) (4)<br>(b) (4) | 29 Sep 2020 21:37:29 |

**US3212013****Folder: Concomitant Procedures (1)****Form: Concomitant Procedures (2)****Generated On: 26 Nov 2020 10:46:15****Indication**

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| User closed query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the MedHistory eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. MedHistory) as appropriate, otherwise clarify..' (Site from DM).             | (b) (4), (b) (6)    | 24 Nov 2020 10:31:58 |
| Query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the MedHistory eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. MedHistory) as appropriate, otherwise clarify..' answered with 'updated' (Site from DM). | afifah Ayub (b) (4) | 02 Nov 2020 14:23:16 |
| DataPoint Un-verified.   | afifah Ayub (b) (4) | 02 Nov 2020 14:23:07 |
| User entered 'Medical History (MH)' reason for change: Data Entry Error  | afifah Ayub (b) (4) | 02 Nov 2020 14:23:07 |
| User opened query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the MedHistory eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. MedHistory) as appropriate, otherwise clarify..' (Site from DM).             | (b) (4), (b) (6)    | 01 Nov 2020 04:33:05 |
| User closed query 'Pleas update indication to Uterine Fibroids. ' (Site from CRA).   | (b) (4), (b) (6)    | 23 Oct 2020 14:42:44 |
| DataPoint Verified.  | (b) (4), (b) (6)    | 23 Oct 2020 14:42:36 |
| Query 'Pleas update indication to Uterine Fibroids. ' answered with 'updated' (Site from CRA).   | afifah Ayub (b) (4) | 14 Oct 2020 17:23:52 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error   | afifah Ayub (b) (4) | 14 Oct 2020 17:23:46 |
| User opened query 'Pleas update indication to Uterine Fibroids. ' (Site from CRA).   | (b) (4), (b) (6)    | 14 Oct 2020 16:38:32 |
| User entered 'Medical History (MH)'  | afifah Ayub (b) (4) | 29 Sep 2020 21:37:29 |

US3212013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:46:15

If indication is Other, specify

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| DataPoint Un-verified.                                 | Afifah Ayub (b) (4) | 02 Nov 2020 14:23:07 |
|  | (b) (4)             |                      |
| User entered empty; reason for change Data Entry Error | Afifah Ayub (b) (4) | 02 Nov 2020 14:23:07 |
|  | (b) (4)             |                      |
| DataPoint Verified.                                    | (b) (4), (b) (6)    | 23 Oct 2020 14:42:39 |
|  |                     |                      |
| DataPoint Un-verified.                                 | Afifah Ayub (b) (4) | 14 Oct 2020 17:23:46 |
|  | (b) (4)             |                      |
| User entered 'Uterine Fibroids' reason for change:     | Afifah Ayub (b) (4) | 14 Oct 2020 17:23:46 |
| Data Entry Error                                       | (b) (4)             |                      |
| DataPoint Verified.                                    | (b) (4), (b) (6)    | 14 Oct 2020 16:38:34 |
|  |                     |                      |
| User entered empty.                                    | Afifah Ayub (b) (4) | 29 Sep 2020 21:37:29 |
|  | (b) (4)             |                      |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[SAEID](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 14:57:44 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered<br>'USA-US115-2020-MRNA-1273-P301000003' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

**Serious**

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 14:57:46 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'Yes (Y)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:57:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:57:57 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 14:58:07 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'Yes (Y)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:15 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:16 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's First Name](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 14:58:20 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered 'Vicki'    | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's Last Name](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 14:58:22 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered 'Miller'   | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: Street](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: City](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: State](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: Postal Code](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator Country](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 14 Oct 2020 15:00:09 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 03:27:59 |
| User entered 'US' (non-conformant).              | System           | 01 Sep 2020 15:51:15 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '7' | System | 24 Nov 2020 13:00:43 |
| User entered '6' | System | 06 Nov 2020 16:16:58 |
| User entered '5' | System | 27 Oct 2020 14:30:17 |
| User entered '4' | System | 16 Oct 2020 00:34:39 |
| User entered '3' | System | 02 Oct 2020 12:31:47 |
| User entered '2' | System | 30 Sep 2020 15:29:40 |
| User entered '1' | System | 01 Sep 2020 15:51:15 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[SAEID](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 14:57:44 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered<br>'USA-US115-2020-MRNA-1273-P301000003' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

**Serious**

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 14:57:46 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'Yes (Y)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:57:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:57:57 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 14:58:07 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'Yes (Y)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:15 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:16 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's First Name](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 14:58:20 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered 'Vicki'    | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's Last Name](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 14:58:22 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered 'Miller'   | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: Street](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: City](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: State](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: Postal Code](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator Country](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 14 Oct 2020 15:00:09 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 03:27:59 |
| User entered 'US' (non-conformant).              | System           | 01 Sep 2020 15:51:15 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '7' | System | 24 Nov 2020 13:00:43 |
| User entered '6' | System | 06 Nov 2020 16:16:58 |
| User entered '5' | System | 27 Oct 2020 14:30:17 |
| User entered '4' | System | 16 Oct 2020 00:34:39 |
| User entered '3' | System | 02 Oct 2020 12:31:47 |
| User entered '2' | System | 30 Sep 2020 15:29:40 |
| User entered '1' | System | 01 Sep 2020 15:51:15 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 10:46:15**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 14 Oct 2020 15:02:46 |
| User entered '01/Sep/2020 11:51' | System           | 01 Sep 2020 15:51:15 |

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:46:15

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| User entered 'I'     | (b) (4), (b) (6) | 01 Sep 2020 15:51:15 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[SAEID](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 14:57:44 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered<br>'USA-US115-2020-MRNA-1273-P301000003' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

**Serious**

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 14:57:46 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'Yes (Y)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:57:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:57:57 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 14:58:07 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'Yes (Y)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:15 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:16 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's First Name](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 14:58:20 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered 'Vicki'    | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's Last Name](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 14:58:22 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered 'Miller'   | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: Street](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: City](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: State](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: Postal Code](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator Country](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 14 Oct 2020 15:00:09 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 03:27:59 |
| User entered 'US' (non-conformant).              | System           | 01 Sep 2020 15:51:15 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '7' | System | 24 Nov 2020 13:00:43 |
| User entered '6' | System | 06 Nov 2020 16:16:58 |
| User entered '5' | System | 27 Oct 2020 14:30:17 |
| User entered '4' | System | 16 Oct 2020 00:34:39 |
| User entered '3' | System | 02 Oct 2020 12:31:47 |
| User entered '2' | System | 30 Sep 2020 15:29:40 |
| User entered '1' | System | 01 Sep 2020 15:51:15 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 26 Nov 2020 10:46:15**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| User entered '30/Sep/2020 15:29' | System           | 30 Sep 2020 15:29:40 |

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:46:15

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Oct 2020 00:34:31 |
|                      |                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
|                      |                  |                      |
| User entered 'I'     | (b) (4), (b) (6) | 30 Sep 2020 15:29:40 |
|                      |                  |                      |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[SAEID](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 14:57:44 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered<br>'USA-US115-2020-MRNA-1273-P301000003' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

**Serious**

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 14:57:46 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'Yes (Y)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:57:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:57:57 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 14:58:07 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'Yes (Y)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:15 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:16 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's First Name](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 14:58:20 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered 'Vicki'    | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's Last Name](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 14:58:22 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered 'Miller'   | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: Street](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: City](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: State](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: Postal Code](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator Country](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 14 Oct 2020 15:00:09 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 03:27:59 |
| User entered 'US' (non-conformant).              | System           | 01 Sep 2020 15:51:15 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '7' | System | 24 Nov 2020 13:00:43 |
| User entered '6' | System | 06 Nov 2020 16:16:58 |
| User entered '5' | System | 27 Oct 2020 14:30:17 |
| User entered '4' | System | 16 Oct 2020 00:34:39 |
| User entered '3' | System | 02 Oct 2020 12:31:47 |
| User entered '2' | System | 30 Sep 2020 15:29:40 |
| User entered '1' | System | 01 Sep 2020 15:51:15 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 26 Nov 2020 10:46:15**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| User entered '02/Oct/2020 08:31' | System           | 02 Oct 2020 12:31:47 |

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:46:15

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Oct 2020 00:34:31 |
|                      |                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
|                      |                  |                      |
| User entered 'I'     | (b) (4), (b) (6) | 02 Oct 2020 12:31:47 |
|                      |                  |                      |
|                      |                  |                      |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[SAEID](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 14:57:44 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered<br>'USA-US115-2020-MRNA-1273-P301000003' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

**Serious**

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 14:57:46 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'Yes (Y)' | System           | 01 Sep 2020 15:50:28 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:57:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:57:57 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 14:58:07 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'Yes (Y)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:15 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:16 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's First Name](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 14:58:20 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered 'Vicki'    | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's Last Name](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 14:58:22 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered 'Miller'   | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: Street](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: City](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: State](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: Postal Code](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator Country](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 14 Oct 2020 15:00:09 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 03:27:59 |
| User entered 'US' (non-conformant).              | System           | 01 Sep 2020 15:51:15 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '7' | System | 24 Nov 2020 13:00:43 |
| User entered '6' | System | 06 Nov 2020 16:16:58 |
| User entered '5' | System | 27 Oct 2020 14:30:17 |
| User entered '4' | System | 16 Oct 2020 00:34:39 |
| User entered '3' | System | 02 Oct 2020 12:31:47 |
| User entered '2' | System | 30 Sep 2020 15:29:40 |
| User entered '1' | System | 01 Sep 2020 15:51:15 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (4)**

**Generated On: 26 Nov 2020 10:46:15**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '15/Oct/2020 20:34' | System | 16 Oct 2020 00:34:39 |

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:46:15

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 27 Oct 2020 14:30:07 |
|                      |                  |                      |
| User entered 'I'     | (b) (4), (b) (6) | 16 Oct 2020 00:34:39 |
|                      |                  |                      |
|                      |                  |                      |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[SAEID](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 14:57:44 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered<br>'USA-US115-2020-MRNA-1273-P301000003' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

**Serious**

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 14:57:46 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'Yes (Y)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:57:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:57:57 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 14:58:07 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'Yes (Y)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:15 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:16 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's First Name](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 14:58:20 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered 'Vicki'    | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's Last Name](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 14:58:22 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered 'Miller'   | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: Street](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: City](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: State](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: Postal Code](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator Country](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 14 Oct 2020 15:00:09 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 03:27:59 |
| User entered 'US' (non-conformant).              | System           | 01 Sep 2020 15:51:15 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '7' | System | 24 Nov 2020 13:00:43 |
| User entered '6' | System | 06 Nov 2020 16:16:58 |
| User entered '5' | System | 27 Oct 2020 14:30:17 |
| User entered '4' | System | 16 Oct 2020 00:34:39 |
| User entered '3' | System | 02 Oct 2020 12:31:47 |
| User entered '2' | System | 30 Sep 2020 15:29:40 |
| User entered '1' | System | 01 Sep 2020 15:51:15 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (5)**

**Generated On: 26 Nov 2020 10:46:15**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27/Oct/2020 10:30' | System | 27 Oct 2020 14:30:17 |

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 10:46:15

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 06 Nov 2020 16:16:45 |
|                      |                  |                      |
| User entered 'I'     | (b) (4), (b) (6) | 27 Oct 2020 14:30:17 |
|                      |                  |                      |
|                      |                  |                      |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[SAEID](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 14:57:44 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered<br>'USA-US115-2020-MRNA-1273-P301000003' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

**Serious**

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 14:57:46 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'Yes (Y)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:57:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:57:57 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 14:58:07 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'Yes (Y)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:15 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:16 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's First Name](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 14:58:20 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered 'Vicki'    | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's Last Name](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 14:58:22 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered 'Miller'   | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: Street](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: City](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: State](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: Postal Code](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator Country](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 14 Oct 2020 15:00:09 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 03:27:59 |
| User entered 'US' (non-conformant).              | System           | 01 Sep 2020 15:51:15 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '7' | System | 24 Nov 2020 13:00:43 |
| User entered '6' | System | 06 Nov 2020 16:16:58 |
| User entered '5' | System | 27 Oct 2020 14:30:17 |
| User entered '4' | System | 16 Oct 2020 00:34:39 |
| User entered '3' | System | 02 Oct 2020 12:31:47 |
| User entered '2' | System | 30 Sep 2020 15:29:40 |
| User entered '1' | System | 01 Sep 2020 15:51:15 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (6)**

**Generated On: 26 Nov 2020 10:46:15**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06/Nov/2020 11:16' | System | 06 Nov 2020 16:16:58 |

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 10:46:15

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:00:32 |
|                      |                  |                      |
| User entered 'I'     | (b) (4), (b) (6) | 06 Nov 2020 16:16:58 |
|                      |                  |                      |
|                      |                  |                      |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[SAEID](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 14:57:44 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered<br>'USA-US115-2020-MRNA-1273-P301000003' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

**Serious**

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 14:57:46 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'Yes (Y)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:57:55 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:57:57 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 14:58:07 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'Yes (Y)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:15 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 14:58:16 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered 'No (N)' | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's First Name](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 14:58:20 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered 'Vicki'    | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's Last Name](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 14:58:22 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered 'Miller'   | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: Street](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: City](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: State](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Site Address: Postal Code](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 14 Oct 2020 15:02:49 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 21:42:51 |
| Amendment Manager: User entered empty.     | System           | 14 Sep 2020 21:42:51 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 15:51:07 |
| User entered (b) (6)                       | System           | 01 Sep 2020 15:50:28 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator Country](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 14 Oct 2020 15:00:09 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 30 Sep 2020 15:29:25 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 03:27:59 |
| User entered 'US' (non-conformant).              | System           | 01 Sep 2020 15:51:15 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '7' | System | 24 Nov 2020 13:00:43 |
| User entered '6' | System | 06 Nov 2020 16:16:58 |
| User entered '5' | System | 27 Oct 2020 14:30:17 |
| User entered '4' | System | 16 Oct 2020 00:34:39 |
| User entered '3' | System | 02 Oct 2020 12:31:47 |
| User entered '2' | System | 30 Sep 2020 15:29:40 |
| User entered '1' | System | 01 Sep 2020 15:51:15 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (7)**

**Generated On: 26 Nov 2020 10:46:15**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24/Nov/2020 08:00' | System | 24 Nov 2020 13:00:43 |

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 10:46:15

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered 'I' | (b) (4), (b) (6) | 24 Nov 2020 13:00:43 |
|                  |                  |                      |
|                  |                  |                      |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[SAEID](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered<br>'USA-US115-2020-MRNA-1273-P301000005' | System           | 30 Sep 2020 14:21:36 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

**Serious**

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'Yes (Y)' | System           | 30 Sep 2020 14:21:36 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'No (N)' | System           | 30 Sep 2020 14:21:36 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'No (N)' | System           | 30 Sep 2020 14:21:36 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'Yes (Y)' | System           | 30 Sep 2020 14:21:36 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'No (N)' | System           | 30 Sep 2020 14:21:36 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'No (N)' | System           | 30 Sep 2020 14:21:36 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'No (N)' | System           | 30 Sep 2020 14:21:36 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'Vicki' | System           | 30 Sep 2020 14:21:36 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's Last Name](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'Miller' | System           | 30 Sep 2020 14:21:36 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator Country](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'US'   | System           | 30 Sep 2020 15:29:40 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[SAEID](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered<br>'USA-US115-2020-MRNA-1273-P301000005' | System           | 30 Sep 2020 14:21:36 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

**Serious**

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'Yes (Y)' | System           | 30 Sep 2020 14:21:36 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'No (N)' | System           | 30 Sep 2020 14:21:36 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'No (N)' | System           | 30 Sep 2020 14:21:36 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'Yes (Y)' | System           | 30 Sep 2020 14:21:36 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'No (N)' | System           | 30 Sep 2020 14:21:36 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'No (N)' | System           | 30 Sep 2020 14:21:36 |



**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'No (N)' | System           | 30 Sep 2020 14:21:36 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'Vicki' | System           | 30 Sep 2020 14:21:36 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator's Last Name](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'Miller' | System           | 30 Sep 2020 14:21:36 |

**US3212013**

**Folder: SAE USA-US115-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:46:15**

[Investigator Country](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Oct 2020 15:04:02 |
| User entered 'US'   | System           | 30 Sep 2020 15:29:40 |