

US3802168 (Prod: UPMC University Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:58:29

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US3802168

Form: Participant Creation

Data signed: (b) (4) 14 Sep 2020 16:30:51

Generated On: 10 Jun 2021 09:58:29

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Participant ID

US3802168

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

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US3802168

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 14 Sep 2020 16:30:51

Generated On: 10 Jun 2021 09:58:29

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 08 SEP 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                                    |

US3802168

Folder: Screening

Form: Demographics

Data signed: (b) (4) 14 Sep 2020 16:30:51

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| Date of Birth (MMM yyyy)                  | (b) (6) 1979   |
| Age                                       | 41   |
| Age Units                                 | YEARS  |
| Age (Derived)                             | 41   |
| Sex                                       | Female <input type="radio"/><br>Male <input checked="" 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  |

US3802168

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 14 Sep 2020 16:30:51

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 8 SEP 2020                                   |
| Month and Year of Informed Consent (derived)    | SEP 2020                                     |
| Year of Informed Consent (derived)              | 2020   |
| Protocol Version                                | Amendment 1 <input type="radio"/>            |
|   | Amendment 2 <input type="radio"/>            |
|   | Amendment 3 <input checked="" 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  |

US3802168

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 14 Sep 2020 16:30:51

Generated On: 10 Jun 2021 09:58:29

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3802168

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 14 Sep 2020 16:30:51

Generated On: 10 Jun 2021 09:58:29

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Were any significant conditions reported?

Yes ☒

No ☐

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US3802168

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| Condition   | SEASONAL ALLERGIES   |
| Start date (dd MMM yyyy)                          |  |
| Start date completely unknown                     | True   |
| 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)                    |  |
| Start Year (derived)                              |  |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |



US3802168

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| Condition   | ALLERGIES TO DUST, MOLD,<br>AND CATS                             |
| Start date (dd MMM yyyy)                          |  |
| Start date completely unknown                     | True   |
| 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)                    |  |
| Start Year (derived)                              |  |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

US3802168

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| Condition   | CHRONIC SINUSITIS  |
| Start date (dd MMM yyyy)                          | UN UNK 2000  |
| 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 2000   |
| Start Year (derived)                              | 2000   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

US3802168

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| Condition   | FREQUENT HEART BURN  |
| 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)                                     | _____  |

US3802168

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| Condition   | ULCERATIVE COLITIS   |
| 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)                               |  |

US3802168

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| Condition   | ANXIETY  |
| Start date (dd MMM yyyy)                                | UN UNK 2014  |
| 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 2014   |
| Start Year (derived)                                    | 2014   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

US3802168

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| Condition   | HERNIATED DISC SURGERY   |
| Start date (dd MMM yyyy)                          | UN UNK 2019  |
| 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 2019  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2019   |
| Start Year (derived)                              | 2019   |
| Stop Month and Year (derived)                     | JAN 2019   |
| Stop Year (derived)                               | 2019   |

US3802168

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| Condition   | BENIGN LIVER LESION  |
| Start date (dd MMM yyyy)                          | UN UNK 2008  |
| 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 2008   |
| Start Year (derived)                              | 2008   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

US3802168

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| Condition   | CHRONIC DRY SKIN   |
| Start date (dd MMM yyyy)                          |  |
| Start date completely unknown                     | True   |
| 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)                    |  |
| Start Year (derived)                              |  |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |



US3802168

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| Condition   | CHRONIC DRY FEET   |
| Start date (dd MMM yyyy)                          |  |
| Start date completely unknown                     | True   |
| 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)                    |  |
| Start Year (derived)                              |  |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

US3802168

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 14 Sep 2020 16:30:51

Generated On: 10 Jun 2021 09:58:29

|                                     |  |
|-------------------------------------|--|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>   |
|                                     | No <input type="radio"/>               |
| Date of assessment (dd MMM yyyy)    | 8 SEP 2020                             |
| Time of assessment (00:00-23:59)    | 10:43 (24 HR)                          |
| Vital Signs Date and Time (derived) | 8 SEP 2020 10:43                       |
| Height (xxx.x)                      | 71.5 in                                |
| Weight (xxx.x)                      | 247 lb                                 |
| BMI (xxx.x)                         | 34.04041 kg/m <sup>2</sup>             |
| BMI units                           | KG/M2                                  |
| Temperature (xxx.x)                 | 97.3 F                                 |
| Route of measurement                | Oral <input type="radio"/>             |
|                                     | Axillary <input type="radio"/>         |
|                                     | Other <input checked="" type="radio"/> |
| If Other, specify                   | INFRARED                               |
| Pulse (xxx)                         | 70 beats/min                           |
| Pulse units                         | BPM                                    |
| Respiratory Rate (xxx)              | 18 breaths/min                         |
| Respiratory Rate units              | BREATHS/MIN                            |
| Systolic Blood Pressure (xxx)       | 126 mmHg                               |
| Systolic Blood Pressure units       | MMHG                                   |
| Diastolic Blood Pressure (xxx)      | 86 mmHg                                |
| Diastolic Blood Pressure units      | MMHG                                   |
| Height (derived)                    |  |
| Weight (derived)                    |  |

US3802168

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 14 Sep 2020 16:30:51

Generated On: 10 Jun 2021 09:58:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3802168

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Sep 2020 16:30:51

Generated On: 10 Jun 2021 09:58:29

### 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

SCHOOL AGE CHILDREN WHO  
HAVE IN PERSON  
INSTRUCTION.

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

**No Risk Identified** False

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

19 of 2786

US3802168

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Sep 2020 16:30:51

Generated On: 10 Jun 2021 09:58:29

|  |       |
|--|-------|
| <b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) | False |
| <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)       | True  |
| <b>Resides in a single family home</b> (i.e., detached housing)  | False |
| <b>Other</b>   | False |
| <b>Specify</b>   |       |

US3802168

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 14 Sep 2020 16:30:51

Generated On: 10 Jun 2021 09:58:29

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 8 SEP 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                                  |

US3802168

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

What was the date of randomization? (dd MMM yyyy) 08 SEP 2020

What was the participant's randomization number? 112311

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 ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

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



US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|                                     |  |
|-------------------------------------|--|
| 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)    | 8 SEP 2020   |
| Time of assessment (00:00-23:59)    | 10:43 (24 HR)  |
| Vital Signs Date and Time (derived) | 8 SEP 2020 10:43   |
| Temperature (xxx.x)                 | 97.3 F   |
| Route of measurement                | Oral <input type="radio"/><br>Axillary <input type="radio"/><br>Other <input checked="" type="radio"/> |
| If Other, specify                   | INFRARED   |
| Pulse (xxx)                         | 70 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 18 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 126 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 86 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|                                     |  |
|-------------------------------------|--|
| 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)    | 8 SEP 2020   |
| Time of assessment (00:00-23:59)    | 11:47 (24 HR)  |
| Vital Signs Date and Time (derived) | 8 SEP 2020 11:47   |
| Temperature (xxx.x)                 | 97.3 F   |
| Route of measurement                | Oral <input type="radio"/><br>Axillary <input type="radio"/><br>Other <input checked="" type="radio"/> |
| If Other, specify                   | INFRARED   |
| Pulse (xxx)                         | 62 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 18 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 128 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 88 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3802168

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 14 Sep 2020 16:30:51

Generated On: 10 Jun 2021 09:58:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3802168

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 14 Sep 2020 16:30:51

Generated On: 10 Jun 2021 09:58:29

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 11:15 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 11:15

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3802168

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Sep 2020 16:30:50

Generated On: 10 Jun 2021 09:58:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 SEP 2020

Collection time (00:00-23:59)

10:55 (24 HR)

Collection date and time (derived)

8 SEP 2020 10:55

US3802168

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Sep 2020 16:30:51

Generated On: 10 Jun 2021 09:58:29

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 8 SEP 2020                         |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 10:51                           | 8 SEP 2020 10:51                   |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3802168

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 14 Sep 2020 16:30:50

Generated On: 10 Jun 2021 09:58:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**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

97.3 °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 SEP 2020 11:50

PC Open Date & Time

08 SEP 2020 11:35

PC Close Date & Time

08 SEP 2020 14:05



US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**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 97.0 °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        | 08 SEP 2020 19:18 |
| PC Open Date & Time  | 08 SEP 2020 15:00 |
| PC Close Date & Time | 09 SEP 2020 11:59 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**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

97.2 °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

09 SEP 2020 19:10

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**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

96.7 °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):

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

10 SEP 2020 20:11

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**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

97.3 °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):

To **TREAT** pain or fever that has already occurred

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

11 SEP 2020 18:40

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**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

97.5 °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):

To **TREAT** pain or fever that has already occurred

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

12 SEP 2020 19:07

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:29

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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.

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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

97.5 °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

13 SEP 2020 19:30

---

PC Open Date & Time

13 SEP 2020 12:00

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PC Close Date & Time

14 SEP 2020 11:59

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US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**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.

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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

97.7 °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):

To **TREAT** pain or fever that has already occurred

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

14 SEP 2020 21:56

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

DAY 8

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

97.7 °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):

To **TREAT** pain or fever that has already occurred

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

15 SEP 2020 21:30

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59



US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

DAY 9

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 <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 97.9 °F                              |
| Was any <b>MEDICATION TAKEN</b> today for pain or fever? | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |

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

|   |       |
|---|-------|
| To <b>TREAT</b> pain or fever that has already occurred | False |
| To <b>PREVENT</b> pain or fever from occurring          | True  |

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 16 SEP 2020 20:27 |
| PC Open Date & Time  | 16 SEP 2020 12:00 |
| PC Close Date & Time | 17 SEP 2020 11:59 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

DAY 10

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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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

97.7 °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):

To **TREAT** pain or fever that has already occurred

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

17 SEP 2020 18:00

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

DAY 11

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

97.7 °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

18 SEP 2020 19:01

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**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

08 SEP 2020 11:50

PC Open Date & Time

08 SEP 2020 11:35

PC Close Date & Time

08 SEP 2020 14:05

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**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

08 SEP 2020 19:18

PC Open Date & Time

08 SEP 2020 15:00

PC Close Date & Time

09 SEP 2020 11:59

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**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

09 SEP 2020 19:11

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**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

10 SEP 2020 20:11

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**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

11 SEP 2020 18:40

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59



US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**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 SEP 2020 19:07

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**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 SEP 2020 19:30

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**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

14 SEP 2020 21:56

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**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 ☐

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 08 SEP 2020 11:51 |
| PC Open Date & Time  | 08 SEP 2020 11:35 |
| PC Close Date & Time | 08 SEP 2020 14:05 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**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 ☐

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 08 SEP 2020 19:19 |
| PC Open Date & Time  | 08 SEP 2020 15:00 |
| PC Close Date & Time | 09 SEP 2020 11:59 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**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 ☒



US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 09 SEP 2020 19:11 |
| PC Open Date & Time          | 09 SEP 2020 12:00 |
| PC Close Date & Time         | 10 SEP 2020 11:59 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

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 ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

57 of 2786

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 10 SEP 2020 20:12 |
| PC Open Date & Time          | 10 SEP 2020 12:00 |
| PC Close Date & Time         | 11 SEP 2020 11:59 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

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 ☒

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 11 SEP 2020 18:40 |
| PC Open Date & Time          | 11 SEP 2020 12:00 |
| PC Close Date & Time         | 12 SEP 2020 11:59 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

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 ☒

PRODUCTION RELEASE (v12.003

61 of 2786

EAB) (1725)

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 12 SEP 2020 19:08 |
| PC Open Date & Time          | 12 SEP 2020 12:00 |
| PC Close Date & Time         | 13 SEP 2020 11:59 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

63 of 2786



US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

|                      |                   |                              |
|----------------------|-------------------|------------------------------|
|                      |                   | Yes <input type="checkbox"/> |
| PC Time stamp        | 13 SEP 2020 19:32 |                              |
| PC Open Date & Time  | 13 SEP 2020 12:00 |                              |
| PC Close Date & Time | 14 SEP 2020 11:59 |                              |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**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 ☒

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 14 SEP 2020 21:57 |
| PC Open Date & Time          | 14 SEP 2020 12:00 |
| PC Close Date & Time         | 15 SEP 2020 11:59 |

US3802168

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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 ☐

PC Time Stamp 15 SEP 2020 21:30

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3802168

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 15 SEP 2020 21:30

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3802168

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(8)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

DAY 8

Select one response below to indicate the level of your

**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 ☐

PC Time stamp 15 SEP 2020 21:30

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3802168

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 8  |
| Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 15 SEP 2020 21:30  |
| PC Open Date & Time   | 15 SEP 2020 12:00  |
| PC Close Date & Time  | 16 SEP 2020 11:59  |

US3802168

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 9  |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 16 SEP 2020 20:27  |
| PC Open Date & Time   | 16 SEP 2020 12:00  |
| PC Close Date & Time  | 17 SEP 2020 11:59  |



US3802168

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 10   |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 17 SEP 2020 18:00  |
| PC Open Date & Time   | 17 SEP 2020 12:00  |
| PC Close Date & Time  | 18 SEP 2020 11:59  |

US3802168

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 11   |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 18 SEP 2020 19:01  |
| PC Open Date & Time   | 18 SEP 2020 12:00  |
| PC Close Date & Time  | 19 SEP 2020 11:59  |

US3802168

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802168

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802168

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:26:07

Generated On: 10 Jun 2021 09:58:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802168

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802168

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:26:07

Generated On: 10 Jun 2021 09:58:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802168

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:26:07

Generated On: 10 Jun 2021 09:58:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3802168

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 9 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                                  |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|                                     |   |
|-------------------------------------|---|
| 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)    | 9 OCT 2020                                |
| Time of assessment (00:00-23:59)    | 12:56 (24 HR)                             |
| Vital Signs Date and Time (derived) | 9 OCT 2020 12:56                          |
| Temperature (xxx.x)                 | 98.6 F                                    |
| Route of measurement                | Oral <input type="radio"/>                |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input checked="" type="radio"/>    |
| If Other, specify                   | INFRARED                                  |
| Pulse (xxx)                         | 76 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 18 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 138 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 86 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|                                     |  |
|-------------------------------------|--|
| 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)    | 9 OCT 2020                                 |
| Time of assessment (00:00-23:59)    | 13:48 (24 HR)                              |
| Vital Signs Date and Time (derived) | 9 OCT 2020 13:48                           |
| Temperature (xxx.x)                 | 98.1 F                                     |
| Route of measurement                | Oral <input type="radio"/>                 |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input checked="" type="radio"/>     |
| If Other, specify                   | INFRARED                                   |
| Pulse (xxx)                         | 76 beats/min                               |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 18 breaths/min                             |
| Respiratory Rate units              | BREATHS/MIN                                |
| Systolic Blood Pressure (xxx)       | 137 mmHg                                   |
| Systolic Blood Pressure units       | MMHG                                       |
| Diastolic Blood Pressure (xxx)      | 86 mmHg                                    |
| Diastolic Blood Pressure units      | MMHG                                       |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

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.*

US3802168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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) 9 OCT 2020

What was the treatment time? (00:00-23:59) 13:18 (24 HR)

Treatment Date and Time (derived) 9 OCT 2020 13:18

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3802168

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 9 OCT 2020                           |
| Collection time (00:00-23:59)      | 13:08 (24 HR)                        |
| Collection date and time (derived) | 9 OCT 2020 13:08                     |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 9 OCT 2020                         |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 13:09                           | 9 OCT 2020 13:09                   |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**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

98.1 °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 OCT 2020 13:51

PC Open Date & Time

09 OCT 2020 13:38

PC Close Date & Time

09 OCT 2020 16:08

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**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 98.1 °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 OCT 2020 19:46 |
| PC Open Date & Time  | 09 OCT 2020 17:03 |
| PC Close Date & Time | 10 OCT 2020 11:59 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**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

97.9 °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 19:46

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**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

97.9 °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):

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

11 OCT 2020 20:25

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**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

97.5 °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):

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

12 OCT 2020 18:34

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**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

97.5 °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

13 OCT 2020 20:16

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**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

97.7 °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

15 OCT 2020 05:20

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**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

97.9 °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

15 OCT 2020 21:07

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59



US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

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

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 13:52

PC Open Date & Time

09 OCT 2020 13:38

PC Close Date & Time

09 OCT 2020 16:08

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**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

09 OCT 2020 19:46

PC Open Date & Time

09 OCT 2020 17:03

PC Close Date & Time

10 OCT 2020 11:59

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**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

10 OCT 2020 19:47

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**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

11 OCT 2020 20:25

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**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

12 OCT 2020 18:34

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**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

13 OCT 2020 20:16

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**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

15 OCT 2020 05:20

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**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

15 OCT 2020 21:07

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59



US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**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 ☐

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 09 OCT 2020 13:55 |
| PC Open Date & Time  | 09 OCT 2020 13:38 |
| PC Close Date & Time | 09 OCT 2020 16:08 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**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 ☐

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 09 OCT 2020 19:47 |
| PC Open Date & Time  | 09 OCT 2020 17:03 |
| PC Close Date & Time | 10 OCT 2020 11:59 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

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 ☒

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 10 OCT 2020 19:47 |
| PC Open Date & Time          | 10 OCT 2020 12:00 |
| PC Close Date & Time         | 11 OCT 2020 11:59 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

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 ☒

PRODUCTION RELEASE (v12.003

110 of 2786

EAB) (1725)

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 11 OCT 2020 20:25 |
| PC Open Date & Time          | 11 OCT 2020 12:00 |
| PC Close Date & Time         | 12 OCT 2020 11:59 |



US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

112 of 2786

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 12 OCT 2020 18:35 |
| PC Open Date & Time          | 12 OCT 2020 12:00 |
| PC Close Date & Time         | 13 OCT 2020 11:59 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

114 of 2786

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 13 OCT 2020 20:17 |
| PC Open Date & Time          | 13 OCT 2020 12:00 |
| PC Close Date & Time         | 14 OCT 2020 11:59 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

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 ☒

PRODUCTION RELEASE (v12.003

116 of 2786

EAB) (1725)

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 15 OCT 2020 05:21 |
| PC Open Date & Time          | 14 OCT 2020 12:00 |
| PC Close Date & Time         | 15 OCT 2020 11:59 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

118 of 2786

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 15 OCT 2020 21:08 |
| PC Open Date & Time          | 15 OCT 2020 12:00 |
| PC Close Date & Time         | 16 OCT 2020 11:59 |



US3802168

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 8  |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 16 OCT 2020 23:00  |
| PC Open Date & Time   | 16 OCT 2020 12:00  |
| PC Close Date & Time  | 17 OCT 2020 11:59  |

US3802168

Folder: Diary Dose 2 (1)

Form: Underarm Gland\_Day(8)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

DAY 8

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 16 OCT 2020 23:00

PC Open Date and Time 16 OCT 2020 12:00

PC Close Date and Time 17 OCT 2020 11:59

US3802168

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802168

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802168

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802168

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802168

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802168

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3802168

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 9 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                                  |

US3802168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>   |
|   | No <input type="radio"/>               |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 9 NOV 2020                             |
| Time of assessment ( <i>00:00-23:59</i> ) | 13:03 (24 HR)                          |
| Vital Signs Date and Time (derived)       | 9 NOV 2020 13:03                       |
| Temperature ( <i>xxx.x</i> )              | 97.4 F                                 |
| Route of measurement                      | Oral <input type="radio"/>             |
|   | Axillary <input type="radio"/>         |
|   | Other <input checked="" type="radio"/> |
| If Other, specify                         | INFRARED                               |
| Pulse ( <i>xxx</i> )                      | 86 beats/min                           |
| Pulse units                               | BPM                                    |
| Respiratory Rate ( <i>xxx</i> )           | 18 breaths/min                         |
| Respiratory Rate units                    | BREATHS/MIN                            |
| Systolic Blood Pressure ( <i>xxx</i> )    | 136 mmHg                               |
| Systolic Blood Pressure units             | MMHG                                   |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 86 mmHg                                |
| Diastolic Blood Pressure units            | MMHG                                   |
| Height (derived)                          |  |
| Weight (derived)                          |  |

US3802168

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

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.*

US3802168

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 NOV 2020

Collection time (00:00-23:59)

13:13 (24 HR)

Collection date and time (derived)

9 NOV 2020 13:13

US3802168

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☒

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

08 NOV 2020 04:46:17

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3802168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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

16 NOV 2020 19:50:20

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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"/>   |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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23 NOV 2020 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☒

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

26 NOV 2020 05:10:29

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☒

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

05 DEC 2020 12:00:33

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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 checked="" 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 checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 12 DEC 2020 10:20:12   |
| Patient Cloud Open Date & Time  | 10 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 14 DEC 2020 23:59  |

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

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

Date and time of submission

17 DEC 2020 05:42:37

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☒

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

24 DEC 2020 20:50:15

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☒

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 DEC 2020 05:57:29

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☒

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

09 JAN 2021 12:21:45

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59



US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☒

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 JAN 2021 06:10:44

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | 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 <input checked="" 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 checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 21 JAN 2021 05:48:26   |
| Patient Cloud Open Date & Time  | 21 JAN 2021 00:01  |
| Patient Cloud Close Date & Time   | 25 JAN 2021 23:59  |

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☒

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 JAN 2021 05:55:07

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☒

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

04 FEB 2021 06:13:41

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☒

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

12 FEB 2021 05:33:10

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☒

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

18 FEB 2021 19:07:35

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

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

Date and time of submission

27 FEB 2021 20:59:30

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☒

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 MAR 2021 17:59:28

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59



US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☒

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

11 MAR 2021 06:07:28

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☒

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

18 MAR 2021 06:30:43

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☒

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

27 MAR 2021 12:09:05

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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 <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   | 01 APR 2021 01:58:44   |
| Patient Cloud Open Date & Time  | 01 APR 2021 00:01  |
| Patient Cloud Close Date & Time   | 05 APR 2021 23:59  |

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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="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 type="radio"/><br>Yes <input checked="" 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 checked="" type="radio"/> |
| Date and time of submission   | 09 APR 2021 12:33:46   |
| Patient Cloud Open Date & Time  | 08 APR 2021 00:01  |
| Patient Cloud Close Date & Time   | 12 APR 2021 23:59  |

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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="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 type="radio"/><br>Yes <input checked="" 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 checked="" type="radio"/> |
| Date and time of submission   | 15 APR 2021 01:33:50   |
| Patient Cloud Open Date & Time  | 15 APR 2021 00:01  |
| Patient Cloud Close Date & Time   | 19 APR 2021 23:59  |

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

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

Date and time of submission

22 APR 2021 02:24:32

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☒

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

01 MAY 2021 12:00:15

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59



US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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="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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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"/>  |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐ 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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

03 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐  
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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

10 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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 <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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

17 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐ 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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59



US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

01 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐ 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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 JUL 2021 23:59 |

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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="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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 26 JUL 2021 23:59 |



US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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="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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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="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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 AUG 2021 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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="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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 AUG 2021 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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 <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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 26 AUG 2021 00:01 |
|--|-------------------|

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 30 AUG 2021 23:59 |
|---|-------------------|

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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 <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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 13 SEP 2021 23:59 |

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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°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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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16 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 SEP 2021 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 SEP 2021 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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°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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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="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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59



US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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="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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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 <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"/>  |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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 <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"/>  |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 11 NOV 2021 00:01 |
|--|-------------------|

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 NOV 2021 23:59 |
|---|-------------------|

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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 <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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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18 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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="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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2021 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 DEC 2021 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59



US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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="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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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16 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 DEC 2021 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐ 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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 27 DEC 2021 23:59 |

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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="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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JAN 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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="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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59



US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐  
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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 JAN 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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20 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JAN 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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27 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 JAN 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐  
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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 FEB 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 FEB 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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 <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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 FEB 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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 <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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

03 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 14 MAR 2022 23:59 |

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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17 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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°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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 APR 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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14 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 APR 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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21 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 APR 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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"/>  |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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28 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐  
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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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 <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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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 <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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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26 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐ 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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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°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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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°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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUN 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 JUL 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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="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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
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| Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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°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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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14 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUL 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐  
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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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>  | 21 JUL 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 25 JUL 2022 23:59 |



US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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="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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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 <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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

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08 AUG 2022 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐ 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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

11 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐ 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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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18 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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 <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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
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| Please contact your study clinic immediately. Click below to confirm that you have read this 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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| <a href="#">Patient Cloud Open Date &amp; Time</a> | 25 AUG 2022 00:01 |
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| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 AUG 2022 23:59 |
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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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="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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 SEP 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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 <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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59



US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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 <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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐ 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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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06 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 OCT 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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 <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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 OCT 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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°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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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20 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 OCT 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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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|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 27 OCT 2022 00:01 |
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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 31 OCT 2022 23:59 |
|---|-------------------|

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**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 ☐

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

03 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

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US3802168

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

| 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 <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"/>   |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01 |
|--|-------------------|

---

|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 14 NOV 2022 23:59 |
|---|-------------------|

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US3802168

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:58:29

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| No  |  | 27 FEB 2021 20:59:24      |

US3802168

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802168

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802168

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802168

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802168

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:34:03

Generated On: 10 Jun 2021 09:58:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802168

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:34:03

Generated On: 10 Jun 2021 09:58:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802168

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:22:04

Generated On: 10 Jun 2021 09:58:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3802168

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:22:04

Generated On: 10 Jun 2021 09:58:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802168

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 18:40:53

Generated On: 10 Jun 2021 09:58:29

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 8 APR 2021                              |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT4                                  |

US3802168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 18:40:53

Generated On: 10 Jun 2021 09:58:29

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3802168

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 18:40:53

Generated On: 10 Jun 2021 09:58:29

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.*

US3802168

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 18:40:53

Generated On: 10 Jun 2021 09:58:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 APR 2021

Collection time (00:00-23:59)

13:20 (24 HR)

Collection date and time (derived)

8 APR 2021 13:20

US3802168

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 18:40:53

Generated On: 10 Jun 2021 09:58:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3802168**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

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*

**US3802168**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3802168

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Data signed: (b) (4) 23 Apr 2021 18:04:32

Generated On: 10 Jun 2021 09:58:29

|  |  |
|--|--|
| Date of Contact                                  | 19 APR 2021  |
| Time of Contact                                  | 09:00  |
| Date and Time of Contact (derived)               | 19 APR 2021 09:00  |
| Type of Contact                                  | <div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div> |
| Has the subject reported symptoms of SARS-COV-2? | <div>Yes<input type="checkbox"/></div> <div>No<input checked="" type="checkbox"/></div>  |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

|  |  |
|--|--|
| Date of Contact                                  | 26 OCT 2020  |
| Time of Contact                                  | 10:30  |
| Date and Time of Contact (derived)               | 26 OCT 2020 10:30  |
| Type of Contact                                  | <div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div> |
| Has the subject reported symptoms of SARS-COV-2? | <div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>  |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

Symptom Day

|        |                                  |
|--------|----------------------------------|
| Day 1  | <input checked="" type="radio"/> |
| Day 2  | <input type="radio"/>            |
| Day 3  | <input type="radio"/>            |
| Day 4  | <input type="radio"/>            |
| Day 5  | <input type="radio"/>            |
| Day 6  | <input type="radio"/>            |
| Day 7  | <input type="radio"/>            |
| Day 8  | <input type="radio"/>            |
| Day 9  | <input type="radio"/>            |
| Day 10 | <input type="radio"/>            |
| Day 11 | <input type="radio"/>            |
| Day 12 | <input type="radio"/>            |
| Day 13 | <input type="radio"/>            |
| Day 14 | <input type="radio"/>            |
| Day 15 | <input type="radio"/>            |
| Day 16 | <input type="radio"/>            |
| Day 17 | <input type="radio"/>            |
| Day 18 | <input type="radio"/>            |
| Day 19 | <input type="radio"/>            |
| Day 20 | <input type="radio"/>            |
| Day 21 | <input type="radio"/>            |
| Day 22 | <input type="radio"/>            |
| Day 23 | <input type="radio"/>            |
| Day 24 | <input type="radio"/>            |
| Day 25 | <input type="radio"/>            |
| Day 26 | <input type="radio"/>            |
| Day 27 | <input type="radio"/>            |
| Day 28 | <input type="radio"/>            |
| Day 29 | <input type="radio"/>            |
| Day 30 | <input type="radio"/>            |
| Day 31 | <input type="radio"/>            |
| Day 32 | <input type="radio"/>            |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 33      | <input type="checkbox"/>         |
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 26 OCT 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 98 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.4 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

339 of 2786

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input checked="" type="checkbox"/> |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 33      | <input type="checkbox"/>         |
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 27 OCT 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 98 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.9 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

343 of 2786



US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

PRODUCTION RELEASE (v12.003

EAB) (1725)

344 of 2786

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input checked="" type="checkbox"/> |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 33      | <input type="checkbox"/>         |
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 28 OCT 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 98 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.1 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

347 of 2786

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

Date of Visit 26 OCT 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒  
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐  
No ☒

Date of Test 26 OCT 2020

Type of Test Performed Nasopharyngeal Swab ☒  
Nasal Swab ☐  
Saliva Test ☐  
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐  
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐  
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

|  |  |
|--|--|
| Date of Contact                                  | 30 DEC 2020  |
| Time of Contact                                  | 09:52  |
| Date and Time of Contact (derived)               | 30 DEC 2020 09:52  |
| Type of Contact                                  | <div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div> |
| Has the subject reported symptoms of SARS-COV-2? | <div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>  |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Symptom Day

|        |                                  |
|--------|----------------------------------|
| Day 1  | <input checked="" type="radio"/> |
| Day 2  | <input type="radio"/>            |
| Day 3  | <input type="radio"/>            |
| Day 4  | <input type="radio"/>            |
| Day 5  | <input type="radio"/>            |
| Day 6  | <input type="radio"/>            |
| Day 7  | <input type="radio"/>            |
| Day 8  | <input type="radio"/>            |
| Day 9  | <input type="radio"/>            |
| Day 10 | <input type="radio"/>            |
| Day 11 | <input type="radio"/>            |
| Day 12 | <input type="radio"/>            |
| Day 13 | <input type="radio"/>            |
| Day 14 | <input type="radio"/>            |
| Day 15 | <input type="radio"/>            |
| Day 16 | <input type="radio"/>            |
| Day 17 | <input type="radio"/>            |
| Day 18 | <input type="radio"/>            |
| Day 19 | <input type="radio"/>            |
| Day 20 | <input type="radio"/>            |
| Day 21 | <input type="radio"/>            |
| Day 22 | <input type="radio"/>            |
| Day 23 | <input type="radio"/>            |
| Day 24 | <input type="radio"/>            |
| Day 25 | <input type="radio"/>            |
| Day 26 | <input type="radio"/>            |
| Day 27 | <input type="radio"/>            |
| Day 28 | <input type="radio"/>            |
| Day 29 | <input type="radio"/>            |
| Day 30 | <input type="radio"/>            |
| Day 31 | <input type="radio"/>            |
| Day 32 | <input type="radio"/>            |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 33      | <input type="checkbox"/>         |
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 30 DEC 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 100 %       |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.1 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

354 of 2786

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

PRODUCTION RELEASE (v12.003

EAB) (1725)

355 of 2786

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input checked="" type="checkbox"/> |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 33      | <input type="checkbox"/>         |
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 31 DEC 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 98 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.2 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

358 of 2786

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input checked="" type="checkbox"/> |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                      |            |                                  |
|----------------------|------------|----------------------------------|
|                      | Day 33     | <input type="checkbox"/>         |
|                      | Day 34     | <input type="checkbox"/>         |
|                      | Day 35     | <input type="checkbox"/>         |
|                      | Day 36     | <input type="checkbox"/>         |
|                      | Day 37     | <input type="checkbox"/>         |
|                      | Day 38     | <input type="checkbox"/>         |
|                      | Day 39     | <input type="checkbox"/>         |
|                      | Day 40     | <input type="checkbox"/>         |
| Date                 | 1 JAN 2021 |                                  |
| Assessment Not Done  | False      |                                  |
| O2 Saturation        | 97 %       |                                  |
| O2 Saturation Units  | %          |                                  |
| Temperature          | 98.1 F     |                                  |
| Chills               | None       | <input checked="" type="radio"/> |
|                      | Mild       | <input type="radio"/>            |
|                      | Moderate   | <input type="radio"/>            |
|                      | Severe     | <input type="radio"/>            |
|                      | Not Done   | <input type="radio"/>            |
| Cough                | None       | <input checked="" type="radio"/> |
|                      | Mild       | <input type="radio"/>            |
|                      | Moderate   | <input type="radio"/>            |
|                      | Severe     | <input type="radio"/>            |
|                      | Not Done   | <input type="radio"/>            |
| Shortness of Breath  | None       | <input checked="" type="radio"/> |
|                      | Mild       | <input type="radio"/>            |
|                      | Moderate   | <input type="radio"/>            |
|                      | Severe     | <input type="radio"/>            |
|                      | Not Done   | <input type="radio"/>            |
| Difficulty Breathing | None       | <input checked="" type="radio"/> |
|                      | Mild       | <input type="radio"/>            |
|                      | Moderate   | <input type="radio"/>            |
|                      | Severe     | <input type="radio"/>            |

PRODUCTION RELEASE (v12.003

EAB) (1725)

362 of 2786

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input checked="" type="checkbox"/> |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                      |            |                                  |
|----------------------|------------|----------------------------------|
|                      | Day 33     | <input type="checkbox"/>         |
|                      | Day 34     | <input type="checkbox"/>         |
|                      | Day 35     | <input type="checkbox"/>         |
|                      | Day 36     | <input type="checkbox"/>         |
|                      | Day 37     | <input type="checkbox"/>         |
|                      | Day 38     | <input type="checkbox"/>         |
|                      | Day 39     | <input type="checkbox"/>         |
|                      | Day 40     | <input type="checkbox"/>         |
| Date                 | 2 JAN 2021 |                                  |
| Assessment Not Done  | False      |                                  |
| O2 Saturation        | 98 %       |                                  |
| O2 Saturation Units  | %          |                                  |
| Temperature          | 97.6 F     |                                  |
| Chills               | None       | <input checked="" type="radio"/> |
|                      | Mild       | <input type="radio"/>            |
|                      | Moderate   | <input type="radio"/>            |
|                      | Severe     | <input type="radio"/>            |
|                      | Not Done   | <input type="radio"/>            |
| Cough                | None       | <input checked="" type="radio"/> |
|                      | Mild       | <input type="radio"/>            |
|                      | Moderate   | <input type="radio"/>            |
|                      | Severe     | <input type="radio"/>            |
|                      | Not Done   | <input type="radio"/>            |
| Shortness of Breath  | None       | <input checked="" type="radio"/> |
|                      | Mild       | <input type="radio"/>            |
|                      | Moderate   | <input type="radio"/>            |
|                      | Severe     | <input type="radio"/>            |
|                      | Not Done   | <input type="radio"/>            |
| Difficulty Breathing | None       | <input checked="" type="radio"/> |
|                      | Mild       | <input type="radio"/>            |
|                      | Moderate   | <input type="radio"/>            |
|                      | Severe     | <input type="radio"/>            |

PRODUCTION RELEASE (v12.003

EAB) (1725)

366 of 2786

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

PRODUCTION RELEASE (v12.003

EAB) (1725)

367 of 2786



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input checked="" type="checkbox"/> |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                      |            |                                  |
|----------------------|------------|----------------------------------|
|                      | Day 33     | <input type="checkbox"/>         |
|                      | Day 34     | <input type="checkbox"/>         |
|                      | Day 35     | <input type="checkbox"/>         |
|                      | Day 36     | <input type="checkbox"/>         |
|                      | Day 37     | <input type="checkbox"/>         |
|                      | Day 38     | <input type="checkbox"/>         |
|                      | Day 39     | <input type="checkbox"/>         |
|                      | Day 40     | <input type="checkbox"/>         |
| Date                 | 3 JAN 2021 |                                  |
| Assessment Not Done  | False      |                                  |
| O2 Saturation        | 99 %       |                                  |
| O2 Saturation Units  | %          |                                  |
| Temperature          | 97.7 F     |                                  |
| Chills               | None       | <input checked="" type="radio"/> |
|                      | Mild       | <input type="radio"/>            |
|                      | Moderate   | <input type="radio"/>            |
|                      | Severe     | <input type="radio"/>            |
|                      | Not Done   | <input type="radio"/>            |
| Cough                | None       | <input checked="" type="radio"/> |
|                      | Mild       | <input type="radio"/>            |
|                      | Moderate   | <input type="radio"/>            |
|                      | Severe     | <input type="radio"/>            |
|                      | Not Done   | <input type="radio"/>            |
| Shortness of Breath  | None       | <input checked="" type="radio"/> |
|                      | Mild       | <input type="radio"/>            |
|                      | Moderate   | <input type="radio"/>            |
|                      | Severe     | <input type="radio"/>            |
|                      | Not Done   | <input type="radio"/>            |
| Difficulty Breathing | None       | <input checked="" type="radio"/> |
|                      | Mild       | <input type="radio"/>            |
|                      | Moderate   | <input type="radio"/>            |
|                      | Severe     | <input type="radio"/>            |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

370 of 2786

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input checked="" type="checkbox"/> |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                             |             |                                  |
|-----------------------------|-------------|----------------------------------|
|                             | Day 33      | <input type="checkbox"/>         |
|                             | Day 34      | <input type="checkbox"/>         |
|                             | Day 35      | <input type="checkbox"/>         |
|                             | Day 36      | <input type="checkbox"/>         |
|                             | Day 37      | <input type="checkbox"/>         |
|                             | Day 38      | <input type="checkbox"/>         |
|                             | Day 39      | <input type="checkbox"/>         |
|                             | Day 40      | <input type="checkbox"/>         |
| Date                        | 4 JAN 2021  |                                  |
| Assessment Not Done         | False       |                                  |
| O2 Saturation               | 99 %        |                                  |
| O2 Saturation Units         | %           |                                  |
| Temperature                 | 97.6 F      |                                  |
| Chills                      | None        | <input checked="" type="radio"/> |
|                             | Mild        | <input type="radio"/>            |
|                             | Moderate    | <input type="radio"/>            |
|                             | Severe      | <input type="radio"/>            |
|                             | Not Done    | <input type="radio"/>            |
| Cough                       | None        | <input checked="" type="radio"/> |
|                             | Mild        | <input type="radio"/>            |
|                             | Moderate    | <input type="radio"/>            |
|                             | Severe      | <input type="radio"/>            |
|                             | Not Done    | <input type="radio"/>            |
| Shortness of Breath         | None        | <input checked="" type="radio"/> |
|                             | Mild        | <input type="radio"/>            |
|                             | Moderate    | <input type="radio"/>            |
|                             | Severe      | <input type="radio"/>            |
|                             | Not Done    | <input type="radio"/>            |
| Difficulty Breathing        | None        | <input checked="" type="radio"/> |
|                             | Mild        | <input type="radio"/>            |
|                             | Moderate    | <input type="radio"/>            |
|                             | Severe      | <input type="radio"/>            |
| PRODUCTION RELEASE (v12.003 | 374 of 2786 |                                  |
| EAB) (1725)                 |             |                                  |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| Date of Visit   | 30 DEC 2020  |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR?                           | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Date of Test  | 30 DEC 2020  |
| Type of Test Performed  | Nasopharyngeal Swab <input checked="" type="radio"/><br>Nasal Swab <input type="radio"/><br>Saliva Test <input type="radio"/><br>Other <input type="radio"/> |
| Other, specify  |  |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| If yes, provide lab information below   |  |
| Lab/ Institution Test Performed   |  |
| CLIA Certified?   | Yes <input type="radio"/><br>No <input type="radio"/>  |
| COVID-19 Positive (CSA Programming Field Only)                                | 0  |

US3802168

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Feb 2021 14:46:50

Generated On: 10 Jun 2021 09:58:29

| Visit  | Was Saliva Collected?  | Date of Collection |
|--------|------------------------|--------------------|
| Day 3  | NA (COVID-19 Negative) |                    |
| Day 5  | NA (COVID-19 Negative) |                    |
| Day 7  | NA (COVID-19 Negative) |                    |
| Day 9  | NA (COVID-19 Negative) |                    |
| Day 14 | NA (COVID-19 Negative) |                    |
| Day 21 | NA (COVID-19 Negative) |                    |
| Day 28 | NA (COVID-19 Negative) |                    |

US3802168

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

| Visit  | Was Saliva Collected?  | Date of Collection |
|--------|------------------------|--------------------|
| Day 3  | NA (COVID-19 Negative) |                    |
| Day 5  | NA (COVID-19 Negative) |                    |
| Day 7  | NA (COVID-19 Negative) |                    |
| Day 9  | NA (COVID-19 Negative) |                    |
| Day 14 | NA (COVID-19 Negative) |                    |
| Day 21 | NA (COVID-19 Negative) |                    |
| Day 28 | NA (COVID-19 Negative) |                    |

**US3802168**

**Folder: Illness Visit (3)**

**Form: Saliva Collection**

**Generated On: 10 Jun 2021 09:58:29**

| Visit  | Was Saliva Collected? | Date of Collection |
|--------|-----------------------|--------------------|
| Day 3  |                       |                    |
| Day 5  |                       |                    |
| Day 7  |                       |                    |
| Day 9  |                       |                    |
| Day 14 |                       |                    |
| Day 21 |                       |                    |
| Day 28 |                       |                    |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 26 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  | SICKD1                                  |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                                     |  |
|-------------------------------------|--|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>   |
|                                     | No <input type="radio"/>               |
| Date of assessment (dd MMM yyyy)    | 26 OCT 2020                            |
| Time of assessment (00:00-23:59)    | 10:30 (24 HR)                          |
| Vital Signs Date and Time (derived) | 26 OCT 2020 10:30                      |
| Height (xxx.x)                      | ND - Not Done                          |
| Weight (xxx.x)                      | ND - Not Done                          |
| Temperature (xxx.x)                 | 98.4 F                                 |
| Route of measurement                | Oral <input type="radio"/>             |
|                                     | Axillary <input type="radio"/>         |
|                                     | Other <input checked="" type="radio"/> |
| If Other, specify                   | INFARED                                |
| Pulse (xxx)                         | 80 beats/min                           |
| Pulse units                         | BPM                                    |
| Respiratory Rate (xxx)              | 20 breaths/min                         |
| Respiratory Rate units              | BREATHS/MIN                            |
| Systolic Blood Pressure (xxx)       | 149 mmHg                               |
| Systolic Blood Pressure units       | MMHG                                   |
| Diastolic Blood Pressure (xxx)      | 82 mmHg                                |
| Diastolic Blood Pressure units      | MMHG                                   |
| Height (derived)                    |  |
| Weight (derived)                    |  |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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



US3802168

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 OCT 2020

US3802168

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 30 DEC 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | SICKD1                                  |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Mar 2021 16:35:05

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>   |
|   | No <input type="radio"/>               |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 30 DEC 2020                            |
| Time of assessment ( <i>00:00-23:59</i> ) | 09:54 (24 HR)                          |
| Vital Signs Date and Time (derived)       | 30 DEC 2020 09:54                      |
| Height ( <i>xxx.x</i> )                   | ND - Not Done                          |
| Weight ( <i>xxx.x</i> )                   | ND - Not Done                          |
| Temperature ( <i>xxx.x</i> )              | 98.1 F                                 |
| Route of measurement                      | Oral <input type="radio"/>             |
|   | Axillary <input type="radio"/>         |
|   | Other <input checked="" type="radio"/> |
| If Other, specify                         | INFRARED                               |
| Pulse ( <i>xxx</i> )                      | 68 beats/min                           |
| Pulse units                               | BPM                                    |
| Respiratory Rate ( <i>xxx</i> )           | 18 breaths/min                         |
| Respiratory Rate units                    | BREATHS/MIN                            |
| Systolic Blood Pressure ( <i>xxx</i> )    | 169 mmHg                               |
| Systolic Blood Pressure units             | MMHG                                   |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 89 mmHg                                |
| Diastolic Blood Pressure units            | MMHG                                   |
| Height (derived)                          |  |
| Weight (derived)                          |  |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 DEC 2020

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

US3802168

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

30 DEC 2020

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID \_\_\_\_\_

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

|   |                                   |
|---|-----------------------------------|
| 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)                          |                                   |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:29

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.*



**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:58:29**

|  |   |
|--|---|
| Was Blood Sample Taken for Immunologic Assessment of | Yes <input type="checkbox"/>                    |
| SARS_COV-2 Infection?                                | No <input type="checkbox"/>                     |
|  | NA (COVID-19 Negative) <input type="checkbox"/> |

|                    |  |
|--------------------|--|
| Date of Collection |  |
|--------------------|--|

US3802168

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

|                           |                                     |
|---------------------------|-------------------------------------|
| Was this visit performed? | Yes <input type="radio"/>           |
|                           | No <input checked="" type="radio"/> |

Visit date (dd MMM yyyy)

|   |                              |
|---|------------------------------|
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>   |
|   | Clinic <input type="radio"/> |

|            |         |
|------------|---------|
| Folder OID | SICKD28 |
|------------|---------|

US3802168

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

|   |                                   |
|---|-----------------------------------|
| 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)                          |                                   |

US3802168

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:29

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.*

**US3802168**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:58:29**

|  |                        |                          |
|--|------------------------|--------------------------|
| Was Blood Sample Taken for Immunologic Assessment of | Yes                    | <input type="checkbox"/> |
| SARS_COV-2 Infection?                                | No                     | <input type="checkbox"/> |
|  | NA (COVID-19 Negative) | <input type="checkbox"/> |

|                    |  |
|--------------------|--|
| Date of Collection |  |
|--------------------|--|

**US3802168**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

|                           |                              |
|---------------------------|------------------------------|
| Was this visit performed? | Yes <input type="checkbox"/> |
|                           | No <input type="checkbox"/>  |

|                          |  |
|--------------------------|--|
| Visit date (dd MMM yyyy) |  |
|--------------------------|--|

|   |                                 |
|---|---------------------------------|
| Was visit performed at the participant's home or at the clinic? | Home <input type="checkbox"/>   |
|   | Clinic <input type="checkbox"/> |

|            |  |
|------------|--|
| Folder OID |  |
|------------|--|

US3802168

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

|   |                                   |
|---|-----------------------------------|
| 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)                          |                                   |

US3802168

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:29

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.*



US3802168

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:58:29

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

**US3802168**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID \_\_\_\_\_

US3802168

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

|   |                                   |
|---|-----------------------------------|
| 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)                          |                                   |

US3802168

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:29

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.*

**US3802168**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:58:29**

|  |                        |                          |
|--|------------------------|--------------------------|
| Was Blood Sample Taken for Immunologic Assessment of | Yes                    | <input type="checkbox"/> |
| SARS_COV-2 Infection?                                | No                     | <input type="checkbox"/> |
|  | NA (COVID-19 Negative) | <input type="checkbox"/> |

|                    |  |
|--------------------|--|
| Date of Collection |  |
|--------------------|--|

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 5 JAN 2021                              |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | UNBLND_DECIDE                           |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 18:40:53

Generated On: 10 Jun 2021 09:58:29

|   |   |
|---|---|
| Date of updated informed consent ( <i>dd MMM yyyy</i> )               | 5 JAN 2021  |
| N/A - Subject Unblinded under Amendment 5 and Discontinued from Study | False   |
| Was the participant unblinded?  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>  |
| Under what version of the Protocol was the Participant unblinded?     | Amendment 5 <input type="radio"/><br>Amendment 6 or later <input checked="" type="radio"/>                            |
| Date of unblinding ( <i>dd MMM yyyy</i> )                             | 5 JAN 2021  |
| Participant randomization assignment                                  | mRNA-1273 <input type="radio"/><br>Placebo <input checked="" type="radio"/>   |
| Actual Dose 1   | mRNA-1273 <input type="radio"/><br>Placebo <input checked="" type="radio"/><br>Not Administered <input type="radio"/> |
| Actual Dose 2   | mRNA-1273 <input type="radio"/><br>Placebo <input checked="" type="radio"/><br>Not Administered <input type="radio"/> |
| Will participant receive mRNA-1273?                                   | Yes <input checked="" type="radio"/><br>No <input type="radio"/>  |
| Placebo Only Flag   | 1   |
| Continuing with mRNA-1273   | 1   |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|             |          |
|-------------|----------|
| Height      | 177.2 cm |
| Weight      | 243 lb   |
| BMI (xxx.x) | 35.17679 |



US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                                     |  |
|-------------------------------------|--|
| Height                              | 177.2 cm   |
| Weight                              | 243 lb   |
| BMI (xxx.x)                         | 35.17679   |
| 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)    | 5 JAN 2021   |
| Time of assessment (00:00-23:59)    | 16:08 (24 HR)  |
| Vital Signs Date and Time (derived) | 5 JAN 2021 16:08   |
| Temperature (xxx.x)                 | 97.8 F   |
| Route of measurement                | Oral <input type="radio"/><br>Axillary <input type="radio"/><br>Other <input checked="" type="radio"/> |
| If Other, specify                   | INFRARED   |
| Pulse (xxx)                         | 78 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 17 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 135 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 89 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                                     |  |
|-------------------------------------|--|
| Height                              | 177.2 cm   |
| Weight                              | 243 lb   |
| BMI (xxx.x)                         | 35.17679   |
| 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)    | 5 JAN 2021   |
| Time of assessment (00:00-23:59)    | 17:25 (24 HR)  |
| Vital Signs Date and Time (derived) | 5 JAN 2021 17:25   |
| Temperature (xxx.x)                 | 97.0 F   |
| Route of measurement                | Oral <input type="radio"/><br>Axillary <input type="radio"/><br>Other <input checked="" type="radio"/> |
| If Other, specify                   | INFRARED   |
| Pulse (xxx)                         | 82 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 18 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 140 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 90 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 JAN 2021

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

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 5 JAN 2021

What was the treatment time? (00:00-23:59) 16:51 (24 HR)

Treatment Date and Time (derived) 5 JAN 2021 16:51

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 JAN 2021

Collection time (00:00-23:59)

16:45 (24 HR)

Collection date and time (derived)

5 JAN 2021 16:45

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 5 JAN 2021                           |
| Collection time (00:00 - 23:59)    | 16:47                                |
| Collection Date and Time (derived) | 5 JAN 2021 16:47                     |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802168

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3802168

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:26:14

Generated On: 10 Jun 2021 09:58:29

|  |                                      |
|--|--------------------------------------|
| Is the participant continuing to the next visit? | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Continuing Flag                                  | 1                                    |
| OLD29 Placebo Flag                               | 1                                    |

US3802168

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 1 FEB 2021                              |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | OLD29                                   |

US3802168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                                     |   |
|-------------------------------------|---|
| 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)    | 1 FEB 2021                                |
| Time of assessment (00:00-23:59)    | 08:07 (24 HR)                             |
| Vital Signs Date and Time (derived) | 1 FEB 2021 08:07                          |
| Temperature (xxx.x)                 | 96.9 F                                    |
| Route of measurement                | Oral <input type="radio"/>                |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input checked="" type="radio"/>    |
| If Other, specify                   | INFRARED                                  |
| Pulse (xxx)                         | 70 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 20 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 125 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 85 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3802168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

|                                     |  |
|-------------------------------------|--|
| 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)    | 1 FEB 2021                                 |
| Time of assessment (00:00-23:59)    | 08:59 (24 HR)                              |
| Vital Signs Date and Time (derived) | 1 FEB 2021 08:59                           |
| Temperature (xxx.x)                 | 97.5 F                                     |
| Route of measurement                | Oral <input type="radio"/>                 |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input checked="" type="radio"/>     |
| If Other, specify                   | INFRARED                                   |
| Pulse (xxx)                         | 55 beats/min                               |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min                             |
| Respiratory Rate units              | BREATHS/MIN                                |
| Systolic Blood Pressure (xxx)       | 123 mmHg                                   |
| Systolic Blood Pressure units       | MMHG                                       |
| Diastolic Blood Pressure (xxx)      | 73 mmHg                                    |
| Diastolic Blood Pressure units      | MMHG                                       |

US3802168

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

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.*

US3802168

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 1 FEB 2021

What was the treatment time? (00:00-23:59) 08:29 (24 HR)

Treatment Date and Time (derived) 1 FEB 2021 08:29

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3802168

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:26:06

Generated On: 10 Jun 2021 09:58:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802168

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:34:03

Generated On: 10 Jun 2021 09:58:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3802168

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:34:03

Generated On: 10 Jun 2021 09:58:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802168

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 03 Mar 2021 16:35:05

Generated On: 10 Jun 2021 09:58:29

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 1 MAR 2021                              |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | OLD57                                   |

US3802168

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Mar 2021 16:35:05

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>   |
|   | No <input type="radio"/>               |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 1 MAR 2021                             |
| Time of assessment ( <i>00:00-23:59</i> ) | 11:04 (24 HR)                          |
| Vital Signs Date and Time (derived)       | 1 MAR 2021 11:04                       |
| Temperature ( <i>xxx.x</i> )              | 97.4 F                                 |
| Route of measurement                      | Oral <input type="radio"/>             |
|   | Axillary <input type="radio"/>         |
|   | Other <input checked="" type="radio"/> |
| If Other, specify                         | INFRARED                               |
| Pulse ( <i>xxx</i> )                      | 74 beats/min                           |
| Pulse units                               | BPM                                    |
| Respiratory Rate ( <i>xxx</i> )           | 18 breaths/min                         |
| Respiratory Rate units                    | BREATHS/MIN                            |
| Systolic Blood Pressure ( <i>xxx</i> )    | 128 mmHg                               |
| Systolic Blood Pressure units             | MMHG                                   |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 84 mmHg                                |
| Diastolic Blood Pressure units            | MMHG                                   |
| Height (derived)                          |  |
| Weight (derived)                          |  |

US3802168

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Mar 2021 16:35:05

Generated On: 10 Jun 2021 09:58:29

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.*

US3802168

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Mar 2021 16:35:05

Generated On: 10 Jun 2021 09:58:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

1 MAR 2021

Collection time (00:00-23:59)

11:14 (24 HR)

Collection date and time (derived)

1 MAR 2021 11:14

US3802168

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 01 Feb 2021 16:26:05

Generated On: 10 Jun 2021 09:58:29

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3802168

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 12:18:37

Generated On: 10 Jun 2021 09:58:29

AEID

Adverse event

PINS AND NEEDLES FEELING IN  
MOUTH

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)

12 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

04 DEC 2020

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

430 of 2786

US3802168

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 12:18:37

Generated On: 10 Jun 2021 09:58:29

|  |   |
|--|---|
| Number of Days in ICU  |   |
| 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 type="radio"/><br>Related <input checked="" 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   | True  |
| Concomitant Medication   | False   |
| 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)                   | 0   |
| Admitted to ICU Derived (CSA Programming Field Only)                         |   |



US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 12:18:37

Generated On: 10 Jun 2021 09:58:29

|  |  |
|--|--|
| AEID   | USA-US098-2021-MRNA-1273-P30<br>1000004  |
| Adverse event  | EXCISION OF PERIHEPATIC<br>MASS, CASTLEMAN'S DISEASE   |
| 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)                                       | 30 MAR 2021  |
| 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)                         | 30 MAR 2021  |
| 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)                          | 30 MAR 2021  |
| Hospital Discharge Date (dd MMM yyyy)                          | 03 APR 2021  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/><br>Unknown <input type="radio"/>  |
| PRODUCTION RELEASE (v12.003<br>EAB) (1725)                     | 432 of 2786  |

US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 12:18:37

Generated On: 10 Jun 2021 09:58:29

|  |   |
|--|---|
| Number of Days in ICU  |   |
| 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 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   | 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  | PATHOLOGY SHOWED CASTLEMAN'S DISEASE. NO TREATMENT NEEDED JUST FOLLOWUP.  |
| 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   |
| PRODUCTION RELEASE (v12.003 EAB) (1725)                                      |   |
| 433 of 2786  |   |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 14 Sep 2020 16:30:50

Generated On: 10 Jun 2021 09:58:29

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration UNKNOWN

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNKNOWN

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

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

435 of 2786

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                           | UN UNK 2015              |                                  |
| 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"/> |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

Name of Medication VITAMIN E

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 400

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

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

437 of 2786

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                           | UN UNK 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)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

Name of Medication AMMONIUM LACTATE 12%  
TOPICAL CREAM

Prophylaxis Yes ☐  
No ☒

Indication DRY FEET

Dose per administration UNKNOWN

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNKNOWN

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

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

439 of 2786



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                       | UN UNK 2016              |                                  |
| 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"/>            |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

Name of Medication MESALAMINE/ENEMA

Prophylaxis Yes ☐  
No ☒

Indication ULCERATIVE COLITIS

Dose per administration 4/60

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify G/ML

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

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

441 of 2786

EAB) (1725)

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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 checked="" 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 2015              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input checked="" type="checkbox"/> |
|  | No                       | <input type="checkbox"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                     |
| 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"/>            |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

Name of Medication ZYRTEC

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

443 of 2786

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                           | UN UNK 2004              |                                  |
| 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"/> |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

Name of Medication FLUTICASONE PROPIONATE  
50MCG/ ACTUATION NASAL  
SPRAY

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 2

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify SPRAYS / NOSTRIL

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

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

445 of 2786

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input checked="" 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 2004                            |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input checked="" type="checkbox"/> |
|  | No                       | <input type="checkbox"/>            |
| If not Ongoing, End date (dd MMM yyyy)         |                          |                                     |
| Was this medication taken for solicited event? | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| 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"/> |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

Name of Medication AZELASTINE 137 MCG NASAL  
SPRAY

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 2

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify SPRAY / NOSTRIL

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

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

447 of 2786



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input checked="" 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 2020              |                                     |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input checked="" type="checkbox"/> |
|  | No                       | <input type="checkbox"/>            |
| If not Ongoing, End date (dd MMM yyyy)         |                          |                                     |
| 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"/>            |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

Name of Medication BUDESONIDE NASAL  
IRRIGATION

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC SINUSITIS

Dose per administration 0.5

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

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

449 of 2786

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intraocular              | <input type="radio"/>            |
|  | Intramuscular            | <input type="radio"/>            |
|  | Respiratory (Inhalation) | <input type="radio"/>            |
|  | Intralesional            | <input type="radio"/>            |
|  | Intraperitoneal          | <input type="radio"/>            |
|  | Nasal                    | <input checked="" 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 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)               | 1                        |                                  |
| Interval Dosage Unit Number (derived)          | 1                        |                                  |
| Interval Dosage Definition (derived)           | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

Name of Medication SODIUM BICARBONATE -  
SODIUM CHLORIDE - NETI POT  
NASAL RINSE PACKET

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC SINUSITIS

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify PACKET

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

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

451 of 2786

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input checked="" 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 2020              |                                     |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input checked="" type="checkbox"/> |
|  | No                       | <input type="checkbox"/>            |
| If not Ongoing, End date (dd MMM yyyy)         |                          |                                     |
| 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"/>            |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 2000

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

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

453 of 2786

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                           | UN UNK 2018              |                                  |
| 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"/> |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|                                |  |
|--------------------------------|--|
| Name of Medication             | CLOBETASOL 0.05% TOPICAL OINTMENT  |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                     | DRY SKIN   |
| Dose per administration        | UNKNOWN  |
| 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 | UNKNOWN  |
| 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"/>  |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

455 of 2786



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                       | UN UNK 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"/>            |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

Name of Medication ZOLOFT

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 50

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

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

457 of 2786

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                           | UN UNK 2015              |                                  |
| 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"/> |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

Name of Medication ESOMEPRAZOLE MAGNESIUM

Prophylaxis Yes ☐  
No ☒

Indication HEART BURN

Dose per administration 40

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

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

459 of 2786

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                           | UN UNK 2010              |                                  |
| 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"/> |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEAD ACHE, MUSCLE PAIN

Dose per administration 500

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

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

461 of 2786

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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)                           |                          | 10 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) 17 SEP 2020 |                          |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input checked="" type="checkbox"/> |
|  | No                       | <input 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"/>            |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

Name of Medication AMOXICILLIN-CLAVULANATE

Prophylaxis Yes ☐  
No ☒

Indication SINUSITIS

Dose per administration 875/125

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

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

463 of 2786



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                           |                          | 7 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)                   |                          | 2                                |
| Interval Dosage Unit Number (derived)              |                          | 1                                |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PREVENT INFLUENZA  
INFECTION

Dose per administration UNK

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

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

465 of 2786

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intraocular              | <input type="radio"/>            |
|  | Intramuscular            | <input checked="" 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)                           | 31 OCT 2020              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 31 OCT 2020                      |
| 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"/>            |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

Name of Medication PEPCID

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 20

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 \_\_\_\_\_

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

467 of 2786

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                           | 24 NOV 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)                   | 2                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

Name of Medication MIRALAX

Prophylaxis Yes ☒  
No ☐

Indication PREVENTION OF  
POST-OPERATIVE  
CONSTIPATION

Dose per administration 17

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify GRAMS

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

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

469 of 2786

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 18:40:52

Generated On: 10 Jun 2021 09:58:29

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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)                       | 1 APR 2021               |                                     |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)         |                          | 7 APR 2021                          |
| Was this medication taken for solicited event? | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| 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"/> |

US3802168

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Feb 2021 12:34:03

Generated On: 10 Jun 2021 09:58:29

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---



US3802168

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 18:40:53

Generated On: 10 Jun 2021 09:58:29

| Procedure/Surgery date (dd MMM<br>yyyy) | Procedure/Surgery                                       | Indication      | If indication is Other, specify |
|---|---|-----------------|---------------------------------|
| 03 FEB 2021                             | ESOPHAGEAL MANOMETRY                                    | Medical History |                                 |
| 30 MAR 2021                             | EXPLORATORY LAPAROTOMY,<br>EXCISION OF PERIHEPATIC MASS | Medical History |                                 |

US3802168

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 14 Sep 2020 16:30:51

Generated On: 10 Jun 2021 09:58:29

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

US3802168

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 14 Sep 2020 16:30:51

Generated On: 10 Jun 2021 09:58:29

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

|  |                          |
|--|--------------------------|
| AE (specify)                                   | <input type="checkbox"/> |
| SAE (specify)                                  | <input type="checkbox"/> |
| Complete                                       | <input type="checkbox"/> |
| Death  | <input type="checkbox"/> |
| Lost To Follow-up                              | <input type="checkbox"/> |
| Physician decision (specify)                   | <input type="checkbox"/> |
| Pregnancy                                      | <input type="checkbox"/> |
| Protocol deviation (specify)                   | <input type="checkbox"/> |
| Study Terminated By Sponsor                    | <input type="checkbox"/> |
| Withdrawal of consent by participant (specify) | <input type="checkbox"/> |
| Other  | <input type="checkbox"/> |

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 | <input type="checkbox"/> |
| Unknown       | <input type="checkbox"/> |
| Other         | <input type="checkbox"/> |

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

|         |                          |
|---------|--------------------------|
| Yes     | <input type="checkbox"/> |
| No      | <input type="checkbox"/> |
| Unknown | <input type="checkbox"/> |

US3802168

Folder: SAE USA-US098-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 16:29:31

Generated On: 10 Jun 2021 09:58:29

|  |  |
|--|--|
| SAEID  | USA-US098-2021-MRNA-1273-P301000004                              |
| 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                                      | JUDITH   |
| Investigator's Last Name                                       | MARTIN   |
| Site Address: Street   | 3420 FIFTH AVE   |
| Site Address: City   | PITTSBURGH   |
| Site Address: State  | PA   |
| Site Address: Postal Code                                      | 15213  |
| Investigator Country   | US   |
| E2B Transmit Flag (Derived/Hidden)                             | 2  |

US3802168

Folder: SAE USA-US098-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 16:29:31

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| SAEID   | USA-US098-2021-MRNA-1273-P301000004                              |
| 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   | JUDITH   |
| Investigator's Last Name  | MARTIN   |
| Site Address: Street  | 3420 FIFTH AVE   |
| Site Address: City  | PITTSBURGH   |
| Site Address: State   | PA   |
| Site Address: Postal Code   | 15213  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 2  |
| Date of submission (Pre-filled from custom function)  | 20/APR/2021 14:22  |
| 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   |

US3802168

Folder: SAE USA-US098-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 16:29:31

Generated On: 10 Jun 2021 09:58:29

|   |  |
|---|--|
| SAEID   | USA-US098-2021-MRNA-1273-P301000004                              |
| 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   | JUDITH   |
| Investigator's Last Name  | MARTIN   |
| Site Address: Street  | 3420 FIFTH AVE   |
| Site Address: City  | PITTSBURGH   |
| Site Address: State   | PA   |
| Site Address: Postal Code   | 15213  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 2  |
| Date of submission (Pre-filled from custom function)  | 29/APR/2021 11:21  |
| 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   |

Audit

US3802168 (Prod: UPMC University Center)

**US3802168**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:58:29**

[Participant ID](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                                  | 14 Sep 2020 16:30:52 |
| User entered 'US3802168'  | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 08 Sep 2020 14:34:52 |



US3802168

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:58:29

[Was this visit performed?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:08:11 |

US3802168

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:58:29

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                                       | 28 Apr 2021 03:10:34 |
| User signature succeeded.  | Judith Martin (b) (4)                                  | 14 Sep 2020 16:30:52 |
| User entered '08 SEP 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 08 Sep 2020 14:34:53 |

**US3802168**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded.      | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:08:11 |

**US3802168**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Folder OID](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered 'SCRN' | System           | 08 Sep 2020 15:08:11 |

US3802168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:29

Date of Birth (MMM yyyy)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                                       | 28 Apr 2021 03:10:34 |
| User signature succeeded.  | Judith Martin (b) (4)                                  | 14 Sep 2020 16:30:52 |
| User entered (b) (6) 1979' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 08 Sep 2020 14:34:54 |

US3802168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:29

[Age](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '41'         | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:08:52 |

**US3802168**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:29**

[Age Units](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered 'YEARS' | System           | 08 Sep 2020 15:08:52 |

**US3802168**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:29**

[Age \(Derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered '41' | System           | 08 Sep 2020 15:09:05 |



**US3802168**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:29**

[Sex](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Male (M)'   | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:08:52 |

US3802168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:29

[Ethnicity](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded.                                      | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:08:52 |

**US3802168**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:29**

[White](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'I'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:08:52 |

**US3802168**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:29**

[Black](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:08:52 |

**US3802168**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:29**

[Asian](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:08:52 |

US3802168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:29

[American Indian or Alaska Native](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:08:52 |

**US3802168**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:29**

[Native Hawaiian or other Pacific Islander](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:08:52 |

**US3802168**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:29**

[Other](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:08:52 |



US3802168

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:29

If race is Other, specify

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:08:52 |

**US3802168**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:29**

[Unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:08:52 |

**US3802168**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:29**

[Not reported](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:08:52 |

US3802168

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:29

Date of Informed Consent (*dd MMM yyyy*)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '8 Sep 2020' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:09:05 |

**US3802168**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:58:29**

[Month and Year of Informed Consent \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered 'Sep 2020' | System           | 08 Sep 2020 15:09:05 |

**US3802168**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:58:29**

[Year of Informed Consent \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered '2020' | System           | 08 Sep 2020 15:09:05 |

**US3802168**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:58:29**

[Protocol Version](#)

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded.      | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Amendment 3 (3)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:09:05 |

US3802168

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:29

[Was participant enrolled in the study?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:09:05 |



**US3802168**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:58:29**

[If No, indicate reason for screen fail](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:09:05 |

**US3802168**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:58:29**

If reason for screen fail is Other, specify

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:09:05 |

US3802168

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:29

[Was this participant screened previously?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:09:05 |

**US3802168**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:58:29**

[If Yes, previous participant number](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                                       | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                                  | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 08 Sep 2020 14:34:53 |

**US3802168**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:58:29**

[Enrollment Trigger](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered 'I'  | System           | 08 Sep 2020 15:09:11 |

US3802168

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:58:29

[Did the participant meet all eligibility criteria?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:09:11 |

US3802168

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:58:29

[Were any significant conditions reported?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:12:33 |

US3802168

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:58:29

[Condition](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 28 Apr 2021 03:10:34 |
| User signature succeeded.  | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| 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)  | 08 Sep 2020 15:14:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)  | 08 Sep 2020 15:14:50 |
| Data point term sent to Coder  | System                | 08 Sep 2020 15:14:00 |
| User entered 'Seasonal allergies'  | Emily Carney (b) (4)  | 08 Sep 2020 15:13:00 |



**US3802168**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:13:00 |

**US3802168**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'I'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:13:00 |

**US3802168**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Condition ongoing at study entry](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:13:00 |

**US3802168**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:58:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:13:00 |

**US3802168**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:13:00 |

**US3802168**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:13:00 |

**US3802168**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:13:00 |

**US3802168**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:13:00 |



**US3802168**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:13:00 |

US3802168

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:29

[Condition](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 28 Apr 2021 03:10:34 |
| User signature succeeded.   | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Multiple allergies, LLT: Multiple allergies - version MedDRA\\23.0. | Coder Import (b) (4)  | 09 Sep 2020 21:22:43 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4)  | 09 Sep 2020 21:22:43 |
| Data point term sent to Coder   | System                | 08 Sep 2020 15:14:00 |
| User entered 'Allergies to dust, mold, and cats'  | Emily Carney (b) (4)  | 08 Sep 2020 15:13:11 |

**US3802168**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:13:11 |

**US3802168**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'I'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:13:11 |

**US3802168**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Condition ongoing at study entry](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:13:11 |

**US3802168**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:58:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:13:11 |

**US3802168**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:13:11 |

**US3802168**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:13:11 |



**US3802168**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:13:11 |

**US3802168**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:13:11 |

**US3802168**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:13:11 |

US3802168

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:58:29

[Condition](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 28 Apr 2021 03:10:34 |
| User signature succeeded.  | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Chronic sinusitis, LLT: Chronic sinusitis - version MedDRA\\23.0. | Coder Import (b) (4)  | 08 Sep 2020 15:14:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)  | 08 Sep 2020 15:14:50 |
| Data point term sent to Coder  | System                | 08 Sep 2020 15:14:01 |
| User entered 'Chronic sinusitis'   | Emily Carney (b) (4)  | 08 Sep 2020 15:13:27 |

**US3802168**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2000' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:13:27 |

**US3802168**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:13:27 |

**US3802168**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Condition ongoing at study entry](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:13:27 |

**US3802168**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:58:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:13:27 |



**US3802168**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:13:27 |

**US3802168**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered 'Jan 2000' | System           | 08 Sep 2020 15:13:27 |

**US3802168**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered '2000' | System           | 08 Sep 2020 15:13:27 |

**US3802168**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:13:27 |

**US3802168**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:13:27 |

US3802168

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:58:29

[Condition](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 28 Apr 2021 03:10:34 |
| User signature succeeded.   | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0. | Coder Import (b) (4)  | 08 Sep 2020 15:19:47 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4)  | 08 Sep 2020 15:19:47 |
| Data point term sent to Coder   | System                | 08 Sep 2020 15:15:03 |
| User entered 'Frequent heart burn'  | Emily Carney (b) (4)  | 08 Sep 2020 15:14:06 |

**US3802168**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2010' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:14:06 |

**US3802168**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:14:06 |



**US3802168**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Condition ongoing at study entry](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:14:06 |

**US3802168**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:58:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:14:06 |

US3802168

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:58:29

[Stop date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:14:06 |

**US3802168**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered 'Jan 2010' | System           | 08 Sep 2020 15:14:06 |

**US3802168**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered '2010' | System           | 08 Sep 2020 15:14:06 |

**US3802168**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:14:06 |

**US3802168**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:14:06 |

US3802168

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:58:29

[Condition](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 28 Apr 2021 03:10:34 |
| User signature succeeded.  | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis ulcerative, LLT: Ulcerative colitis - version MedDRA\\23.0. | Coder Import (b) (4)  | 08 Sep 2020 15:15:47 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)  | 08 Sep 2020 15:15:47 |
| Data point term sent to Coder  | System                | 08 Sep 2020 15:15:03 |
| User entered 'Ulcerative colitis'  | Emily Carney (b) (4)  | 08 Sep 2020 15:14:20 |



**US3802168**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2010' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:14:20 |

**US3802168**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:14:20 |

**US3802168**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Condition ongoing at study entry](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:14:20 |

**US3802168**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:58:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:14:20 |

**US3802168**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:14:20 |

**US3802168**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered 'Jan 2010' | System           | 08 Sep 2020 15:14:20 |

**US3802168**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered '2010' | System           | 08 Sep 2020 15:14:20 |

**US3802168**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:14:20 |



**US3802168**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:14:20 |

US3802168

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:58:29

[Condition](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 28 Apr 2021 03:10:34 |
| User signature succeeded.  | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0. | Coder Import (b) (4)  | 08 Sep 2020 15:15:47 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)  | 08 Sep 2020 15:15:47 |
| Data point term sent to Coder  | System                | 08 Sep 2020 15:15:05 |
| User entered 'Anxiety'   | Emily Carney (b) (4)  | 08 Sep 2020 15:14:33 |

**US3802168**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2014' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:14:33 |

**US3802168**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:14:33 |

**US3802168**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Condition ongoing at study entry](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:14:33 |

**US3802168**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:58:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:14:33 |

**US3802168**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:14:33 |

**US3802168**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered 'Jan 2014' | System           | 08 Sep 2020 15:14:33 |



**US3802168**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered '2014' | System           | 08 Sep 2020 15:14:33 |

**US3802168**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:14:33 |

**US3802168**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:14:33 |

US3802168

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:58:29

[Condition](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 28 Apr 2021 03:10:34 |
| User signature succeeded.   | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Intervertebral disc operation, LLT: Intervertebral disc operation - version MedDRA\\23.0. | Coder Import (b) (4)  | 08 Sep 2020 15:15:46 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)  | 08 Sep 2020 15:15:46 |
| Data point term sent to Coder   | System                | 08 Sep 2020 15:15:07 |
| User entered 'Herniated disc surgery'   | Emily Carney (b) (4)  | 08 Sep 2020 15:14:59 |

**US3802168**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2019' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:14:59 |

**US3802168**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:14:59 |

**US3802168**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:58:29**

[Condition ongoing at study entry](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:14:59 |

**US3802168**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:58:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2019' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:14:59 |



**US3802168**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:14:59 |

**US3802168**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered 'Jan 2019' | System           | 08 Sep 2020 15:14:59 |

**US3802168**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered '2019' | System           | 08 Sep 2020 15:14:59 |

**US3802168**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered 'Jan 2019' | System           | 08 Sep 2020 15:14:59 |

**US3802168**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered '2019' | System           | 08 Sep 2020 15:14:59 |

US3802168

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:58:29

[Condition](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 28 Apr 2021 03:10:34 |
| User signature succeeded.   | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatic and hepatobiliary disorders NEC, PT: Hepatic lesion, LLT: Hepatic lesion - version MedDRA\\23.0. | Coder Import (b) (4)  | 08 Sep 2020 15:56:47 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4)  | 08 Sep 2020 15:56:47 |
| Data point term sent to Coder   | System                | 08 Sep 2020 15:16:08 |
| User entered 'Benign liver lesion'  | Emily Carney (b) (4)  | 08 Sep 2020 15:15:22 |

**US3802168**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2008' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:15:22 |

**US3802168**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:15:22 |



**US3802168**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:58:29**

[Condition ongoing at study entry](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:15:22 |

**US3802168**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:58:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:15:22 |

**US3802168**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:15:22 |

**US3802168**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered 'Jan 2008' | System           | 08 Sep 2020 15:15:22 |

**US3802168**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered '2008' | System           | 08 Sep 2020 15:15:22 |

**US3802168**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:15:22 |

**US3802168**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:15:22 |

US3802168

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:58:29

[Condition](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 28 Apr 2021 03:10:34 |
| User signature succeeded.  | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermal and epidermal conditions NEC, PT: Dry skin, LLT: Dry skin - version MedDRA\\23.0. | Coder Import (b) (4)  | 08 Sep 2020 15:16:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)  | 08 Sep 2020 15:16:50 |
| Data point term sent to Coder  | System                | 08 Sep 2020 15:16:08 |
| User entered 'Chronic dry skin'  | Emily Carney (b) (4)  | 08 Sep 2020 15:15:34 |



**US3802168**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:15:34 |

**US3802168**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'I'          | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:15:34 |

**US3802168**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:58:29**

[Condition ongoing at study entry](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:15:34 |

**US3802168**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:58:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:15:34 |

**US3802168**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:15:34 |

**US3802168**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:15:34 |

**US3802168**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:15:34 |

**US3802168**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:15:34 |



**US3802168**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 08 Sep 2020 15:15:34 |

US3802168

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:58:29

[Condition](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 28 Apr 2021 03:10:34 |
| User signature succeeded.  | Judith Martin (b) (4) | 01 Feb 2021 16:26:14 |
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermal and epidermal conditions NEC, PT: Dry skin, LLT: Dry skin - version MedDRA\\23.0. | Coder Import (b) (4)  | 12 Nov 2020 13:15:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.  | Coder Import (b) (4)  | 12 Nov 2020 13:15:46 |
| Data point term sent to Coder  | System                | 11 Nov 2020 16:26:09 |
| User entered 'Chronic dry feet'  | Emily Carney (b) (4)  | 11 Nov 2020 16:25:48 |

**US3802168**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered empty.       | Emily Carney (b) (4)<br>(b) (4)  | 11 Nov 2020 16:25:48 |

**US3802168**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'I'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 11 Nov 2020 16:25:48 |

**US3802168**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:58:29**

[Condition ongoing at study entry](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 11 Nov 2020 16:25:48 |

**US3802168**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:58:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 01 Feb 2021 16:26:14 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 11 Nov 2020 16:25:48 |

**US3802168**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop date completely unknown](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered '0'          | Emily Carney (b) (4)<br>(b) (4)  | 11 Nov 2020 16:25:48 |

**US3802168**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 11 Nov 2020 16:25:48 |



**US3802168**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:58:29**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 11 Nov 2020 16:25:48 |

**US3802168**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 11 Nov 2020 16:25:48 |

**US3802168**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:58:29**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered empty. | System           | 11 Nov 2020 16:25:48 |

US3802168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Were vital signs assessed?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:09:56 |

**US3802168**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

**Date of assessment** (*dd MMM yyyy*)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '8 Sep 2020' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:09:56 |

**US3802168**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

**Time of assessment (00:00-23:59)**

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '10:43'      | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:09:56 |

**US3802168**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered '8 Sep 2020 10:43' | System           | 08 Sep 2020 15:09:56 |

US3802168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Height (xxx.x)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User entered '71.5' in    | (b) (4)               |                      |
|                           | Emily Carney (b) (4)  | 08 Sep 2020 15:09:56 |
|                           | (b) (4)               |                      |
| DataPoint set to visible. | System                | 08 Sep 2020 15:09:11 |



US3802168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Weight (xxx.x)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '247' lb     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:09:56 |
| DataPoint set to visible. | (b) (4)<br>System               | 08 Sep 2020 15:09:11 |

US3802168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

BMI (xxx.x)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered '34.04041'   | System           | 08 Sep 2020 15:09:56 |
| DataPoint set to visible. | System           | 08 Sep 2020 15:09:11 |

**US3802168**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[BMI units](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered 'kg/m2'      | System           | 08 Sep 2020 15:09:56 |
| DataPoint set to visible. | System           | 08 Sep 2020 15:09:11 |

US3802168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Temperature (xxx.x)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 14 Sep 2020 16:30:52 |
| User entered '97.3' F     | Emily Carney (b) (4)<br>(b) (4)  | 08 Sep 2020 15:09:56 |

**US3802168**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Route of measurement](#)

| Audit                        | User                            | Time (GMT)           |
|------------------------------|---------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded.    | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Other (Other)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:09:56 |

US3802168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[If Other, specify](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Infrared'   | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:09:56 |

**US3802168**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Pulse \(xxx\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '70'         | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:09:56 |

**US3802168**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered 'bpm' | System           | 08 Sep 2020 15:09:56 |



US3802168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '18'         | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:09:56 |

US3802168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered 'breaths/min' | System           | 08 Sep 2020 15:09:56 |

US3802168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Systolic Blood Pressure (xxx)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 14 Sep 2020 16:30:52 |
| User entered '126'        | Emily Carney (b) (4)<br>(b) (4)  | 08 Sep 2020 15:09:56 |

**US3802168**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered 'mmHg' | System           | 08 Sep 2020 15:09:56 |

US3802168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '86'         | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:09:56 |

**US3802168**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
| User entered 'mmHg' | System           | 08 Sep 2020 15:09:56 |

US3802168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
|                   |                  |                      |

US3802168

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:10:34 |
|                   |                  |                      |



**US3802168**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:58:29**

[Was the physical examination performed?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:10:22 |

US3802168

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:29

Date of examination (*dd MMM yyyy*)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '8 Sep 2020' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:10:22 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:12:12 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:12:12 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:12:12 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:12:12 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:12:12 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:12:12 |



US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:12:12 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:12:12 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:12:12 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:12:12 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:12:12 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

[Other](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:12:12 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

[Specify](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 28 Apr 2021 03:10:34 |
| User signature succeeded.  | Judith Martin (b) (4)<br>(b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'School age children who have in person instruction.' | Emily Carney (b) (4)<br>(b) (4)  | 08 Sep 2020 15:12:12 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

No Risk Identified

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:12:12 |



US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:12:12 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

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

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:12:12 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:12:12 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'I'          | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:12:12 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

[Resides in a single family home](#) (i.e., detached housing)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:12:12 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

[Other](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:12:12 |

US3802168

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:29

[Specify](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 03:10:34 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:12:12 |

**US3802168**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Was this visit performed?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:11:07 |



US3802168

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:58:29

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '8 Sep 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:11:07 |

US3802168

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:58:29

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                                       | Time (GMT)           |
|--------------------------------|--|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded.      | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:11:07 |

**US3802168**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'VISIT1' | System           | 08 Sep 2020 15:11:07 |

US3802168

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:29

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

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                                       | 27 Mar 2021 12:17:58 |
| User signature succeeded.  | Judith Martin (b) (4)                                  | 14 Sep 2020 16:30:52 |
| User entered '08 SEP 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 08 Sep 2020 14:49:43 |

US3802168

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:29

[What was the participant's randomization number?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                                       | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                                  | 14 Sep 2020 16:30:52 |
| User entered '112311'     | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 08 Sep 2020 14:49:43 |

US3802168

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:29

[In what Cohort was the participant enrolled?](#)

| Audit   | User   | Time (GMT)           |
|---|--|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)                                       | 27 Mar 2021 12:17:58 |
| User signature succeeded.                             | Judith Martin (b) (4)                                  | 14 Sep 2020 16:30:52 |
| User entered '>=18 and <65 years and not at risk (1)' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 08 Sep 2020 14:49:43 |

US3802168

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:29

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:16:20 |

US3802168

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:29

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:16:20 |



US3802168

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:29

Severe obesity (body mass index > or = 40kg/m2

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:16:20 |

US3802168

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:29

Diabetes (Type I, Type 2, or gestational)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:16:20 |

**US3802168**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:58:29**

[Liver Disease](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:16:20 |

US3802168

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:29

Human Immunodeficiency Virus (HIV) infection

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 27 Mar 2021 12:17:58 |
| User signature succeeded.   | Judith Martin (b) (4)           | 01 Feb 2021 16:26:14 |
| User closed query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6)     | 08 Jan 2021 06:45:39 |
| Query 'Per CDM: This field requires a Yes or No response. Please complete. ' answered with 'Participant is HIV negative according to their medical history. ' (Site from DM). | Emily Carney (b) (4)<br>(b) (4) | 07 Jan 2021 16:35:21 |
| User entered 'No (N)'   | Emily Carney (b) (4)<br>(b) (4) | 07 Jan 2021 16:35:12 |
| User opened query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).  | (b) (4), (b) (6)                | 09 Dec 2020 21:39:13 |
| Amendment Manager: DataPoint set to visible.  | System                          | 19 Sep 2020 05:37:26 |
| Amendment Manager inserted this DataPoint.  | System                          | 19 Sep 2020 05:37:25 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:29

Height

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 27 Mar 2021 12:17:58 |
| User signature succeeded.  | Judith Martin (b) (4)       | 01 Feb 2021 16:26:14 |
| User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field height and weight and remove the units accordingly. ' (Site from DM). Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field height and weight and remove the units accordingly. ' answered with 'done' (Site from DM). | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 23:16:09 |
| Signature has been broken.   | Jennifer Nagg (b) (4)       | 16 Oct 2020 16:38:41 |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | (b) (4)                     | 16 Oct 2020 16:38:35 |
| User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field height and weight and remove the units accordingly. ' (Site from DM). User signature succeeded.  | Jennifer Nagg (b) (4)       | 16 Oct 2020 16:38:35 |
| User entered '71.5' in   | (b) (4), (b) (6)            | 16 Oct 2020 09:44:05 |
|  | Judith Martin (b) (4)       | 14 Sep 2020 16:30:52 |
|  | (b) (4)                     |                      |
|  | Emily Carney (b) (4)        | 08 Sep 2020 15:55:03 |
|  | (b) (4)                     |                      |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:29

Weight

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Mar 2021 12:17:58 |
| User signature succeeded.   | Judith Martin (b) (4) | 01 Feb 2021 16:26:14 |
| Signature has been broken.  | (b) (4)               |                      |
|   | Jennifer Nagg (b) (4) | 16 Oct 2020 16:38:35 |
|   | (b) (4)               |                      |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Jennifer Nagg (b) (4) | 16 Oct 2020 16:38:35 |
| User signature succeeded.   | (b) (4)               |                      |
|   | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|   | (b) (4)               |                      |
| User entered '247' lb   | Emily Carney (b) (4)  | 08 Sep 2020 15:55:03 |
|   | (b) (4)               |                      |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:29

Height

| Audit  | User  | Time (GMT)                                   |
|--|---|--|
| Data hard locked.  | (b) (4), (b) (6)                              | 27 Mar 2021 12:17:58                         |
| User signature succeeded.  | Judith Martin (b) (4)                         | 01 Feb 2021 16:26:14                         |
| User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field height and weight and remove the units accordingly. ' (Site from DM). Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field height and weight and remove the units accordingly. ' answered with 'done' (Site from DM). | (b) (4)<br>(b) (4), (b) (6)                   | 29 Oct 2020 23:16:09                         |
| Signature has been broken.   | Jennifer Nagg (b) (4)                         | 16 Oct 2020 16:38:41                         |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | (b) (4)                                       | 16 Oct 2020 16:38:35                         |
| User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field height and weight and remove the units accordingly. ' (Site from DM). User signature succeeded.  | Jennifer Nagg (b) (4)<br>(b) (4), (b) (6)     | 16 Oct 2020 09:44:05                         |
| User entered '71.5' in   | Judith Martin (b) (4)<br>Emily Carney (b) (4) | 14 Sep 2020 16:30:52<br>08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:29

[Weight](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Mar 2021 12:17:58 |
| User signature succeeded.   | Judith Martin (b) (4) | 01 Feb 2021 16:26:14 |
| Signature has been broken.  | (b) (4)               |                      |
|   | Jennifer Nagg (b) (4) | 16 Oct 2020 16:38:35 |
|   | (b) (4)               |                      |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Jennifer Nagg (b) (4) | 16 Oct 2020 16:38:35 |
| User signature succeeded.   | (b) (4)               |                      |
|   | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|   | (b) (4)               |                      |
| User entered '247' lb   | Emily Carney (b) (4)  | 08 Sep 2020 15:55:03 |
|   | (b) (4)               |                      |



US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Timepoint](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)                | 27 Mar 2021 12:17:58 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Were vital signs assessed?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '8 Sep 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

Time of assessment (00:00-23:59)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '10:43'      | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered '8 Sep 2020 10:43' | System           | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

Temperature (xxx.x)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '97.3' F     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Route of measurement](#)

| Audit                        | User                                       | Time (GMT)           |
|------------------------------|--|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded.    | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Other (Other)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[If Other, specify](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Infrared'   | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |



US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Pulse \(xxx\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '70'         | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'bpm' | System           | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '18'         | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'breaths/min' | System           | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

Systolic Blood Pressure (xxx)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '126'        | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'mmHg' | System           | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '86'         | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'mmHg' | System           | 08 Sep 2020 15:55:03 |



US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:29

Height

| Audit  | User  | Time (GMT)                                   |
|--|---|--|
| Data hard locked.  | (b) (4), (b) (6)                              | 27 Mar 2021 12:17:58                         |
| User signature succeeded.  | Judith Martin (b) (4)                         | 01 Feb 2021 16:26:14                         |
| User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field height and weight and remove the units accordingly. ' (Site from DM). Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field height and weight and remove the units accordingly. ' answered with 'done' (Site from DM). | (b) (4)<br>(b) (4), (b) (6)                   | 29 Oct 2020 23:16:09                         |
| Signature has been broken.   | Jennifer Nagg (b) (4)                         | 16 Oct 2020 16:38:41                         |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | (b) (4)                                       | 16 Oct 2020 16:38:35                         |
| User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field height and weight and remove the units accordingly. ' (Site from DM). User signature succeeded.  | Jennifer Nagg (b) (4)<br>(b) (4), (b) (6)     | 16 Oct 2020 09:44:05                         |
| User entered '71.5' in   | Judith Martin (b) (4)<br>Emily Carney (b) (4) | 14 Sep 2020 16:30:52<br>08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:29

[Weight](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Mar 2021 12:17:58 |
| User signature succeeded.   | Judith Martin (b) (4) | 01 Feb 2021 16:26:14 |
| Signature has been broken.  | (b) (4)               |                      |
|   | Jennifer Nagg (b) (4) | 16 Oct 2020 16:38:35 |
|   | (b) (4)               |                      |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Jennifer Nagg (b) (4) | 16 Oct 2020 16:38:35 |
| User signature succeeded.   | (b) (4)               |                      |
|   | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|   | (b) (4)               |                      |
| User entered '247' lb   | Emily Carney (b) (4)  | 08 Sep 2020 15:55:03 |
|   | (b) (4)               |                      |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Timepoint](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                | 27 Mar 2021 12:17:58 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Were vital signs assessed?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '8 Sep 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |

**US3802168**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '11:47'      | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered '8 Sep 2020 11:47' | System           | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

Temperature (xxx.x)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '97.3' F     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |



US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Route of measurement](#)

| Audit                        | User                                       | Time (GMT)           |
|------------------------------|--|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded.    | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Other (Other)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[If Other, specify](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Infrared'   | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Pulse \(xxx\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '62'         | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'bpm' | System           | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 14 Sep 2020 16:30:52 |
| User entered '18'         | Emily Carney (b) (4)<br>(b) (4)  | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'breaths/min' | System           | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

Systolic Blood Pressure (xxx)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 14 Sep 2020 16:30:52 |
| User entered '128'        | Emily Carney (b) (4)<br>(b) (4)  | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'mmHg' | System           | 08 Sep 2020 15:55:03 |



US3802168

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '88'         | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:55:03 |

**US3802168**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'mmHg' | System           | 08 Sep 2020 15:55:03 |

US3802168

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:29

[Was the physical examination performed?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:11:16 |

US3802168

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:29

Date of examination (*dd MMM yyyy*)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '8 Sep 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:11:16 |

US3802168

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

[Was study treatment given?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:16:51 |

US3802168

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

[If No, reason not given](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:16:51 |

US3802168

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 14 Sep 2020 16:30:52 |
| User entered empty.       | Emily Carney (b) (4)<br>(b) (4)  | 08 Sep 2020 15:16:51 |

**US3802168**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:58:29**

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 08 Sep 2020 15:16:51 |



US3802168

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

What was the treatment date? (dd MMM yyyy)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '8 Sep 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:16:51 |

US3802168

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '11:15'      | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:16:51 |

**US3802168**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:58:29**

[Treatment Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered '8 Sep 2020 11:15' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

[Which arm was used to give treatment?](#)

| Audit                              | User                                       | Time (GMT)           |
|------------------------------------|--|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded.          | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:16:51 |

US3802168

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'ONCE' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'INTRAMUSCULAR' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:29

[Was the sample collected?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:10:42 |

US3802168

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:29

Collection date (*dd MMM yyyy*)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '8 Sep 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:10:42 |



US3802168

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:29

Collection time (00:00-23:59)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '10:55'      | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:10:42 |

**US3802168**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:58:29**

[Collection date and time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered '8 Sep 2020 10:55' | System           | 08 Sep 2020 15:10:42 |

US3802168

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:58:29

Collection date (*dd MMM yyyy*)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '8 Sep 2020' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:10:54 |

US3802168

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:29

[Lab Test](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 27 Mar 2021 12:17:58 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:10:54 |

US3802168

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:29

[Was the sample collected?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:10:54 |

US3802168

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:29

Collection time (00:00 - 23:59)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered '10:51'      | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:10:54 |

**US3802168**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Collection date and time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered '8 Sep 2020 10:51' | System           | 08 Sep 2020 15:10:54 |

**US3802168**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Lab Test](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 27 Mar 2021 12:17:58 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:10:54 |



US3802168

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:29

[Was the sample collected?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:10:54 |

US3802168

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:29

Collection time (00:00 - 23:59)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:10:54 |

**US3802168**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered empty. | System           | 08 Sep 2020 15:10:54 |

US3802168

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:58:29

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:10:59 |

**US3802168**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'I'  | System           | 08 Sep 2020 15:10:59 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T11:49:52', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '0492e674-3c44-41a9-9a0a-ad0cf9392591' User entered 'Yes (Y)' | System           | 08 Sep 2020 15:50:14 |
|   | System           | 08 Sep 2020 15:50:14 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T11:50:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '0492e674-3c44-41a9-9a0a-ad0cf9392591' User entered '97.3' | System           | 08 Sep 2020 15:50:14 |
|  | System           | 08 Sep 2020 15:50:14 |



US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T11:50:07', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '0492e674-3c44-41a9-9a0a-ad0cf9392591' User entered 'No (N)' | System           | 08 Sep 2020 15:50:14 |
|  | System           | 08 Sep 2020 15:50:14 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T11:50:12', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '0492e674-3c44-41a9-9a0a-ad0cf9392591' User entered '08 Sep 2020 11:50' | System           | 08 Sep 2020 15:50:14 |
|   | System           | 08 Sep 2020 15:50:14 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '08 Sep 2020 11:35' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '08 Sep 2020 14:05' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.                                | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 1, after vaccination (at home)' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T19:17:57', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'dc46b0b4-0544-4882-9988-73e83b59a324' | System           | 08 Sep 2020 23:18:10 |
| User entered 'Yes (Y)'   | System           | 08 Sep 2020 23:18:10 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T19:18:01', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'dc46b0b4-0544-4882-9988-73e83b59a324' User entered '97.0' | System           | 08 Sep 2020 23:18:10 |
|  | System           | 08 Sep 2020 23:18:10 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T19:18:04', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'dc46b0b4-0544-4882-9988-73e83b59a324' | System           | 08 Sep 2020 23:18:10 |
| User entered 'No (N)'  | System           | 08 Sep 2020 23:18:10 |



**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T19:18:08', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'dc46b0b4-0544-4882-9988-73e83b59a324' | System           | 08 Sep 2020 23:18:10 |
| User entered '08 Sep 2020 19:18'   | System           | 08 Sep 2020 23:18:10 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '08 Sep 2020 15:00' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '09 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 2' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-09T19:10:42', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e2d1726f-d81f-4d11-a1c2-93398d36aef7' User entered 'Yes (Y)' | System           | 09 Sep 2020 23:10:54 |
|   | System           | 09 Sep 2020 23:10:54 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-09T19:10:45', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e2d1726f-d81f-4d11-a1c2-93398d36aef7' User entered '97.2' | System           | 09 Sep 2020 23:10:54 |
|  | System           | 09 Sep 2020 23:10:54 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-09T19:10:48', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e2d1726f-d81f-4d11-a1c2-93398d36aef7' | System           | 09 Sep 2020 23:10:54 |
| User entered 'No (N)'  | System           | 09 Sep 2020 23:10:54 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-09T19:10:51', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e2d1726f-d81f-4d11-a1c2-93398d36aef7' User entered '09 Sep 2020 19:10' | System           | 09 Sep 2020 23:10:54 |
|   | System           | 09 Sep 2020 23:10:54 |



US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '09 Sep 2020 12:00' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '10 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 3' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:11:04', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b92f4384-e591-4209-9545-417120843c38' User entered 'Yes (Y)' | System           | 11 Sep 2020 00:11:28 |
|   | System           | 11 Sep 2020 00:11:28 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:11:07', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b92f4384-e591-4209-9545-417120843c38' User entered '96.7' | System           | 11 Sep 2020 00:11:28 |
|  | System           | 11 Sep 2020 00:11:28 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:11:10', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b92f4384-e591-4209-9545-417120843c38' | System           | 11 Sep 2020 00:11:28 |
| User entered 'Yes (Y)'   | System           | 11 Sep 2020 00:11:28 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

To **TREAT** pain or fever that has already occurred

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 06 Mar 2021 23:22:52 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted' (Site from System). | (b) (4)               | 17 Sep 2020 11:55:21 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'  | Lalicia Roman (b) (4) | 16 Sep 2020 14:34:12 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:11:23', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b92f4384-e591-4209-9545-417120843c38'  | (b) (4)               |                      |
| User entered '1'  | System                | 11 Sep 2020 00:11:28 |
|   | System                | 11 Sep 2020 00:11:28 |
|   | System                | 11 Sep 2020 00:11:28 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:11:23', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b92f4384-e591-4209-9545-417120843c38' User entered '0' | System           | 11 Sep 2020 00:11:28 |
|   | System           | 11 Sep 2020 00:11:28 |



**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:11:25', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b92f4384-e591-4209-9545-417120843c38' User entered '10 Sep 2020 20:11' | System           | 11 Sep 2020 00:11:28 |
|   | System           | 11 Sep 2020 00:11:28 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '10 Sep 2020 12:00' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '11 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 4' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:39:46', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c84aa9ec-b705-43f9-97c6-5c337b0ba967' | System           | 11 Sep 2020 22:40:04 |
| User entered 'Yes (Y)'   | System           | 11 Sep 2020 22:40:04 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:39:50', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c84aa9ec-b705-43f9-97c6-5c337b0ba967' User entered '97.3' | System           | 11 Sep 2020 22:40:04 |
|  | System           | 11 Sep 2020 22:40:04 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:39:54', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c84aa9ec-b705-43f9-97c6-5c337b0ba967' | System           | 11 Sep 2020 22:40:04 |
| User entered 'Yes (Y)'   | System           | 11 Sep 2020 22:40:04 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

To **TREAT** pain or fever that has already occurred

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:39:57', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c84aa9ec-b705-43f9-97c6-5c337b0ba967' | System           | 11 Sep 2020 22:40:04 |
| User entered '0'   | System           | 11 Sep 2020 22:40:04 |



US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

To **PREVENT** pain or fever from occurring

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 06 Mar 2021 23:22:52 |
| User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted' (Site from System). | (b) (4), (b) (6)      | 17 Sep 2020 11:55:25 |
| User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).  | Lalicia Roman (b) (4) | 16 Sep 2020 14:34:24 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:39:57', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c84aa9ec-b705-43f9-97c6-5c337b0ba967'  | (b) (4)               |                      |
| User entered '1'  | System                | 11 Sep 2020 22:40:04 |
|   | System                | 11 Sep 2020 22:40:04 |
|   | System                | 11 Sep 2020 22:40:04 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:40:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c84aa9ec-b705-43f9-97c6-5c337b0ba967' | System           | 11 Sep 2020 22:40:04 |
| User entered '11 Sep 2020 18:40'   | System           | 11 Sep 2020 22:40:04 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '11 Sep 2020 12:00' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '12 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 5' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:06:54', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2f17ab13-43e6-4c05-82a9-e01e278247ab' User entered 'Yes (Y)' | System           | 12 Sep 2020 23:07:07 |
|   | System           | 12 Sep 2020 23:07:07 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:06:57', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2f17ab13-43e6-4c05-82a9-e01e278247ab' User entered '97.5' | System           | 12 Sep 2020 23:07:07 |
|  | System           | 12 Sep 2020 23:07:07 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:29

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:06:59', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2f17ab13-43e6-4c05-82a9-e01e278247ab' User entered 'Yes (Y)' | System           | 12 Sep 2020 23:07:07 |
|   | System           | 12 Sep 2020 23:07:07 |



US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:29

To **TREAT** pain or fever that has already occurred

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:07:02', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2f17ab13-43e6-4c05-82a9-e01e278247ab' User entered '0' | System           | 12 Sep 2020 23:07:07 |
|   | System           | 12 Sep 2020 23:07:07 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:29

To **PREVENT** pain or fever from occurring

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 06 Mar 2021 23:22:52 |
| User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted' (Site from System). |                       | 17 Sep 2020 11:55:30 |
| User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).  | Lalicia Roman (b) (4) | 16 Sep 2020 14:34:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:07:02', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2f17ab13-43e6-4c05-82a9-e01e278247ab'  | (b) (4)               |                      |
| User entered '1'  | System                | 12 Sep 2020 23:07:07 |
|   | System                | 12 Sep 2020 23:07:07 |
|   | System                | 12 Sep 2020 23:07:07 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:07:05', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2f17ab13-43e6-4c05-82a9-e01e278247ab' User entered '12 Sep 2020 19:07' | System           | 12 Sep 2020 23:07:07 |
|   | System           | 12 Sep 2020 23:07:07 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '12 Sep 2020 12:00' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '13 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 6' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-13T19:30:21', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '09ac7f78-f6ac-4f03-872e-4a214e7386e1' User entered 'Yes (Y)' | System           | 13 Sep 2020 23:30:33 |
|   | System           | 13 Sep 2020 23:30:33 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-13T19:30:25', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '09ac7f78-f6ac-4f03-872e-4a214e7386e1' User entered '97.5' | System           | 13 Sep 2020 23:30:33 |
|  | System           | 13 Sep 2020 23:30:33 |



US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-13T19:30:27', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '09ac7f78-f6ac-4f03-872e-4a214e7386e1' User entered 'No (N)' | System           | 13 Sep 2020 23:30:33 |
|  | System           | 13 Sep 2020 23:30:33 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-13T19:30:31', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '09ac7f78-f6ac-4f03-872e-4a214e7386e1' User entered '13 Sep 2020 19:30' | System           | 13 Sep 2020 23:30:33 |
|   | System           | 13 Sep 2020 23:30:33 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '13 Sep 2020 12:00' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '14 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 7' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:56:06', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '867caa16-d8d2-4773-9cb3-411e58b45f9a' User entered 'Yes (Y)' | System           | 15 Sep 2020 01:56:22 |
|   | System           | 15 Sep 2020 01:56:22 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:56:10', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '867caa16-d8d2-4773-9cb3-411e58b45f9a' User entered '97.7' | System           | 15 Sep 2020 01:56:22 |
|  | System           | 15 Sep 2020 01:56:22 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:56:13', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '867caa16-d8d2-4773-9cb3-411e58b45f9a' | System           | 15 Sep 2020 01:56:22 |
| User entered 'Yes (Y)'   | System           | 15 Sep 2020 01:56:22 |



US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:29

To **TREAT** pain or fever that has already occurred

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:56:15', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '867caa16-d8d2-4773-9cb3-411e58b45f9a' User entered '0' | System           | 15 Sep 2020 01:56:22 |
|   | System           | 15 Sep 2020 01:56:22 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:29

To **PREVENT** pain or fever from occurring

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 06 Mar 2021 23:22:52 |
| User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted' (Site from System). | (b) (4), (b) (6)      | 17 Sep 2020 11:55:36 |
| User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).  | Lalicia Roman (b) (4) | 16 Sep 2020 14:34:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:56:15', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '867caa16-d8d2-4773-9cb3-411e58b45f9a'  | (b) (4)               |                      |
| User entered '1'  | System                | 15 Sep 2020 01:56:22 |
|   | System                | 15 Sep 2020 01:56:22 |
|   | System                | 15 Sep 2020 01:56:22 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:56:18', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '867caa16-d8d2-4773-9cb3-411e58b45f9a' User entered '14 Sep 2020 21:56' | System           | 15 Sep 2020 01:56:22 |
|   | System           | 15 Sep 2020 01:56:22 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '14 Sep 2020 12:00' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '15 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 15 Sep 2020 01:56:22 |
| User entered 'Day 8' | System           | 15 Sep 2020 01:56:22 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-15T21:30:03', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '005683c0-512a-432b-baad-86540cf6a2d9' | System           | 16 Sep 2020 01:30:34 |
| User entered 'Yes (Y)'   | System           | 16 Sep 2020 01:30:34 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-15T21:30:08', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '005683c0-512a-432b-baad-86540cf6a2d9' User entered '97.7' | System           | 16 Sep 2020 01:30:34 |
|  | System           | 16 Sep 2020 01:30:34 |



US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-15T21:30:12', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '005683c0-512a-432b-baad-86540cf6a2d9' | System           | 16 Sep 2020 01:30:34 |
| User entered 'Yes (Y)'   | System           | 16 Sep 2020 01:30:34 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:58:29

To **TREAT** pain or fever that has already occurred

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-15T21:30:14', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '005683c0-512a-432b-baad-86540cf6a2d9' User entered '0' | System           | 16 Sep 2020 01:30:34 |
|   | System           | 16 Sep 2020 01:30:34 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:58:29

To **PREVENT** pain or fever from occurring

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 06 Mar 2021 23:22:52 |
| User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted' (Site from System). | (b) (4), (b) (6)      | 17 Sep 2020 11:55:40 |
| User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).  | Lalicia Roman (b) (4) | 16 Sep 2020 14:35:04 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-15T21:30:14', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '005683c0-512a-432b-baad-86540cf6a2d9'  | (b) (4)               |                      |
| User entered '1'  | System                | 16 Sep 2020 01:30:34 |
|   | System                | 16 Sep 2020 01:30:34 |
|   | System                | 16 Sep 2020 01:30:34 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-15T21:30:17', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '005683c0-512a-432b-baad-86540cf6a2d9' User entered '15 Sep 2020 21:30' | System           | 16 Sep 2020 01:30:34 |
|   | System           | 16 Sep 2020 01:30:34 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '15 Sep 2020 12:00' | System           | 15 Sep 2020 01:56:22 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '16 Sep 2020 11:59' | System           | 15 Sep 2020 01:56:22 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 15 Sep 2020 01:56:22 |
| User entered 'Day 9' | System           | 15 Sep 2020 01:56:22 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-16T20:27:39', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '671af4cb-0286-4688-a6f0-01e9f9132a50' | System           | 17 Sep 2020 00:27:53 |
| User entered 'Yes (Y)'   | System           | 17 Sep 2020 00:27:53 |



US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-16T20:27:43', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '671af4cb-0286-4688-a6f0-01e9f9132a50' User entered '97.9' | System           | 17 Sep 2020 00:27:53 |
|  | System           | 17 Sep 2020 00:27:53 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-16T20:27:46', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '671af4cb-0286-4688-a6f0-01e9f9132a50' | System           | 17 Sep 2020 00:27:53 |
| User entered 'Yes (Y)'   | System           | 17 Sep 2020 00:27:53 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:58:29

To **TREAT** pain or fever that has already occurred

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-16T20:27:48', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '671af4cb-0286-4688-a6f0-01e9f9132a50' User entered '0' | System           | 17 Sep 2020 00:27:53 |
|   | System           | 17 Sep 2020 00:27:53 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:58:29

To **PREVENT** pain or fever from occurring

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 06 Mar 2021 23:22:52 |
| User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated in conmed. confirmed that participant was contacted and took medication. ' (Site from System). |                      | 18 Nov 2020 15:23:39 |
| User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).  | Emily Carney (b) (4) | 28 Oct 2020 19:09:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-16T20:27:48', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '671af4cb-0286-4688-a6f0-01e9f9132a50'  | (b) (4)              |                      |
| User entered '1'  | System               | 17 Sep 2020 00:27:53 |
|   | System               | 17 Sep 2020 00:27:53 |
|   | System               | 17 Sep 2020 00:27:53 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-16T20:27:51', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '671af4cb-0286-4688-a6f0-01e9f9132a50' | System           | 17 Sep 2020 00:27:53 |
| User entered '16 Sep 2020 20:27'   | System           | 17 Sep 2020 00:27:53 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '16 Sep 2020 12:00' | System           | 15 Sep 2020 01:56:22 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '17 Sep 2020 11:59' | System           | 15 Sep 2020 01:56:22 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.    | System           | 16 Sep 2020 01:30:34 |
| User entered 'Day 10' | System           | 16 Sep 2020 01:30:34 |



US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-17T17:59:47', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c2490758-df41-4910-b722-0798cab3b899' User entered 'Yes (Y)' | System           | 17 Sep 2020 22:00:07 |
|   | System           | 17 Sep 2020 22:00:07 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-17T17:59:51', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c2490758-df41-4910-b722-0798cab3b899' User entered '97.7' | System           | 17 Sep 2020 22:00:07 |
|  | System           | 17 Sep 2020 22:00:07 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-17T17:59:56', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c2490758-df41-4910-b722-0798cab3b899' | System           | 17 Sep 2020 22:00:07 |
| User entered 'Yes (Y)'   | System           | 17 Sep 2020 22:00:07 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:58:29

To **TREAT** pain or fever that has already occurred

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-17T17:59:58', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c2490758-df41-4910-b722-0798cab3b899' User entered '0' | System           | 17 Sep 2020 22:00:07 |
|   | System           | 17 Sep 2020 22:00:07 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:58:29

To **PREVENT** pain or fever from occurring

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 06 Mar 2021 23:22:52 |
| User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated on conmed. confirmed contact and medication taken' (Site from System). | (b) (4), (b) (6)     | 18 Nov 2020 15:23:44 |
| User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).  | Emily Carney (b) (4) | 28 Oct 2020 19:11:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-17T17:59:58', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c2490758-df41-4910-b722-0798cab3b899'  | (b) (4)              |                      |
| User entered '1'  | System               | 17 Sep 2020 22:00:07 |
|   | System               | 17 Sep 2020 22:00:07 |
|   | System               | 17 Sep 2020 22:00:07 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(10)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-17T18:00:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c2490758-df41-4910-b722-0798cab3b899' | System           | 17 Sep 2020 22:00:07 |
| User entered '17 Sep 2020 18:00'   | System           | 17 Sep 2020 22:00:07 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '17 Sep 2020 12:00' | System           | 16 Sep 2020 01:30:34 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '18 Sep 2020 11:59' | System           | 16 Sep 2020 01:30:34 |



US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.    | System           | 17 Sep 2020 00:27:53 |
| User entered 'Day 11' | System           | 17 Sep 2020 00:27:53 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-18T19:01:22', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'f5bb62b7-2930-4d6b-abb7-9fe0052f945c' User entered 'Yes (Y)' | System           | 18 Sep 2020 23:01:30 |
|   | System           | 18 Sep 2020 23:01:30 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-18T19:01:25', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'f5bb62b7-2930-4d6b-abb7-9fe0052f945c' User entered '97.7' | System           | 18 Sep 2020 23:01:30 |
|  | System           | 18 Sep 2020 23:01:30 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-18T19:01:27', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'f5bb62b7-2930-4d6b-abb7-9fe0052f945c' User entered 'No (N)' | System           | 18 Sep 2020 23:01:30 |
|  | System           | 18 Sep 2020 23:01:30 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-18T19:01:28', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'f5bb62b7-2930-4d6b-abb7-9fe0052f945c' User entered '18 Sep 2020 19:01' | System           | 18 Sep 2020 23:01:30 |
|   | System           | 18 Sep 2020 23:01:30 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '18 Sep 2020 12:00' | System           | 17 Sep 2020 00:27:53 |

US3802168

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '19 Sep 2020 11:59' | System           | 17 Sep 2020 00:27:53 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 08 Sep 2020 15:16:51 |



US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T11:50:22', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'd9537ad4-a3ea-4aad-a79f-40e35354b344' | System           | 08 Sep 2020 15:51:00 |
| User entered 'None (1)'  | System           | 08 Sep 2020 15:51:00 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T11:50:35', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'd9537ad4-a3ea-4aad-a79f-40e35354b344' User entered 'No (N)' | System           | 08 Sep 2020 15:51:00 |
|  | System           | 08 Sep 2020 15:51:00 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T11:50:37', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'd9537ad4-a3ea-4aad-a79f-40e35354b344' User entered 'No (N)' | System           | 08 Sep 2020 15:51:00 |
|  | System           | 08 Sep 2020 15:51:00 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T11:50:44', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'd9537ad4-a3ea-4aad-a79f-40e35354b344' | System           | 08 Sep 2020 15:51:00 |
| User entered 'None (1)'  | System           | 08 Sep 2020 15:51:00 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T11:50:58', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'd9537ad4-a3ea-4aad-a79f-40e35354b344' | System           | 08 Sep 2020 15:51:00 |
| User entered '08 Sep 2020 11:50'   | System           | 08 Sep 2020 15:51:00 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '08 Sep 2020 11:35' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '08 Sep 2020 14:05' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.                                | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 1, after vaccination (at home)' | System           | 08 Sep 2020 15:16:51 |



US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T19:18:29', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'f667fa6f-89b3-4921-927b-f92711497832' | System           | 08 Sep 2020 23:18:48 |
| User entered 'None (1)'  | System           | 08 Sep 2020 23:18:48 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T19:18:31', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'f667fa6f-89b3-4921-927b-f92711497832' | System           | 08 Sep 2020 23:18:48 |
| User entered 'No (N)'  | System           | 08 Sep 2020 23:18:48 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T19:18:33', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'f667fa6f-89b3-4921-927b-f92711497832' | System           | 08 Sep 2020 23:18:48 |
| User entered 'No (N)'  | System           | 08 Sep 2020 23:18:48 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T19:18:35', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'f667fa6f-89b3-4921-927b-f92711497832' | System           | 08 Sep 2020 23:18:48 |
| User entered 'None (1)'  | System           | 08 Sep 2020 23:18:48 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T19:18:43', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'f667fa6f-89b3-4921-927b-f92711497832' User entered '08 Sep 2020 19:18' | System           | 08 Sep 2020 23:18:48 |
|   | System           | 08 Sep 2020 23:18:48 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '08 Sep 2020 15:00' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '09 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 2' | System           | 08 Sep 2020 15:16:51 |



US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-09T19:11:03', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '32288123-8d0b-4cc8-aa5f-96c2f14a0098' | System           | 09 Sep 2020 23:11:47 |
| User entered 'Does not interfere with activity (2)'  | System           | 09 Sep 2020 23:11:47 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:29

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-09T19:11:30', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '32288123-8d0b-4cc8-aa5f-96c2f14a0098' User entered 'No (N)' | System           | 09 Sep 2020 23:11:47 |
|  | System           | 09 Sep 2020 23:11:47 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-09T19:11:33', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '32288123-8d0b-4cc8-aa5f-96c2f14a0098' User entered 'No (N)' | System           | 09 Sep 2020 23:11:47 |
|  | System           | 09 Sep 2020 23:11:47 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-09T19:11:39', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '32288123-8d0b-4cc8-aa5f-96c2f14a0098' | System           | 09 Sep 2020 23:11:47 |
| User entered 'None (1)'  | System           | 09 Sep 2020 23:11:47 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-09T19:11:41', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '32288123-8d0b-4cc8-aa5f-96c2f14a0098' User entered '09 Sep 2020 19:11' | System           | 09 Sep 2020 23:11:47 |
|   | System           | 09 Sep 2020 23:11:47 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '09 Sep 2020 12:00' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '10 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 3' | System           | 08 Sep 2020 15:16:51 |



US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:11:30', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '70a8fe23-6f9d-45ff-8131-a81d49474335' | System           | 11 Sep 2020 00:11:46 |
| User entered 'Does not interfere with activity (2)'  | System           | 11 Sep 2020 00:11:46 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:29

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:11:32', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '70a8fe23-6f9d-45ff-8131-a81d49474335' | System           | 11 Sep 2020 00:11:46 |
| User entered 'No (N)'  | System           | 11 Sep 2020 00:11:46 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:11:38', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '70a8fe23-6f9d-45ff-8131-a81d49474335' | System           | 11 Sep 2020 00:11:46 |
| User entered 'No (N)'  | System           | 11 Sep 2020 00:11:46 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:11:40', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '70a8fe23-6f9d-45ff-8131-a81d49474335' | System           | 11 Sep 2020 00:11:46 |
| User entered 'None (1)'  | System           | 11 Sep 2020 00:11:46 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:11:42', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '70a8fe23-6f9d-45ff-8131-a81d49474335' | System           | 11 Sep 2020 00:11:46 |
| User entered '10 Sep 2020 20:11'   | System           | 11 Sep 2020 00:11:46 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '10 Sep 2020 12:00' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '11 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 4' | System           | 08 Sep 2020 15:16:51 |



US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:40:03', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '0114a3ed-26c9-4301-ae11-430c90204d59' | System           | 11 Sep 2020 22:40:27 |
| User entered 'None (1)'  | System           | 11 Sep 2020 22:40:27 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:29

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:40:10', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '0114a3ed-26c9-4301-ae11-430c90204d59' | System           | 11 Sep 2020 22:40:27 |
| User entered 'No (N)'  | System           | 11 Sep 2020 22:40:27 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:40:13', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '0114a3ed-26c9-4301-ae11-430c90204d59' User entered 'No (N)' | System           | 11 Sep 2020 22:40:27 |
|  | System           | 11 Sep 2020 22:40:27 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:40:18', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '0114a3ed-26c9-4301-ae11-430c90204d59' | System           | 11 Sep 2020 22:40:27 |
| User entered 'None (1)'  | System           | 11 Sep 2020 22:40:27 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:40:20', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '0114a3ed-26c9-4301-ae11-430c90204d59' User entered '11 Sep 2020 18:40' | System           | 11 Sep 2020 22:40:27 |
|   | System           | 11 Sep 2020 22:40:27 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '11 Sep 2020 12:00' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '12 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 5' | System           | 08 Sep 2020 15:16:51 |



US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:07:14', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b090603d-c4de-4bda-8bd7-df020106783e' User entered 'None (1)' | System           | 12 Sep 2020 23:07:58 |
|  | System           | 12 Sep 2020 23:07:58 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:29

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:07:20', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b090603d-c4de-4bda-8bd7-df020106783e' User entered 'No (N)' | System           | 12 Sep 2020 23:07:58 |
|  | System           | 12 Sep 2020 23:07:58 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:07:22', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b090603d-c4de-4bda-8bd7-df020106783e' User entered 'No (N)' | System           | 12 Sep 2020 23:07:58 |
|  | System           | 12 Sep 2020 23:07:58 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:07:36', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b090603d-c4de-4bda-8bd7-df020106783e' User entered 'None (1)' | System           | 12 Sep 2020 23:07:58 |
|  | System           | 12 Sep 2020 23:07:58 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:07:37', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b090603d-c4de-4bda-8bd7-df020106783e' User entered '12 Sep 2020 19:07' | System           | 12 Sep 2020 23:07:58 |
|   | System           | 12 Sep 2020 23:07:58 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '12 Sep 2020 12:00' | System           | 08 Sep 2020 15:16:51 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '13 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 6' | System           | 08 Sep 2020 15:16:51 |



US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-13T19:30:44', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '1e1761b9-956f-4fd3-9b3a-c0030d5a993b' | System           | 13 Sep 2020 23:30:58 |
| User entered 'Does not interfere with activity (2)'  | System           | 13 Sep 2020 23:30:58 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:29

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-13T19:30:46', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '1e1761b9-956f-4fd3-9b3a-c0030d5a993b' User entered 'No (N)' | System           | 13 Sep 2020 23:30:58 |
|  | System           | 13 Sep 2020 23:30:58 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-13T19:30:51', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '1e1761b9-956f-4fd3-9b3a-c0030d5a993b' User entered 'No (N)' | System           | 13 Sep 2020 23:30:58 |
|  | System           | 13 Sep 2020 23:30:58 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-13T19:30:53', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '1e1761b9-956f-4fd3-9b3a-c0030d5a993b' User entered 'None (1)' | System           | 13 Sep 2020 23:30:58 |
|  | System           | 13 Sep 2020 23:30:58 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-13T19:30:55', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '1e1761b9-956f-4fd3-9b3a-c0030d5a993b' User entered '13 Sep 2020 19:30' | System           | 13 Sep 2020 23:30:58 |
|   | System           | 13 Sep 2020 23:30:58 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '13 Sep 2020 12:00' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '14 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 7' | System           | 08 Sep 2020 15:16:51 |



US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:56:24', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '027dd9f2-8e51-4734-aedc-b9230437fdb5' | System           | 15 Sep 2020 01:56:39 |
| User entered 'None (1)'  | System           | 15 Sep 2020 01:56:39 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:29

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:56:26', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '027dd9f2-8e51-4734-aedc-b9230437fdb5' User entered 'No (N)' | System           | 15 Sep 2020 01:56:39 |
|  | System           | 15 Sep 2020 01:56:39 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:56:27', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '027dd9f2-8e51-4734-aedc-b9230437fdb5' User entered 'No (N)' | System           | 15 Sep 2020 01:56:39 |
|  | System           | 15 Sep 2020 01:56:39 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:56:33', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '027dd9f2-8e51-4734-aedc-b9230437fdb5' | System           | 15 Sep 2020 01:56:39 |
| User entered 'None (1)'  | System           | 15 Sep 2020 01:56:39 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:56:37', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '027dd9f2-8e51-4734-aedc-b9230437fdb5' User entered '14 Sep 2020 21:56' | System           | 15 Sep 2020 01:56:39 |
|   | System           | 15 Sep 2020 01:56:39 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '14 Sep 2020 12:00' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '15 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 08 Sep 2020 15:16:51 |



US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T11:51:06', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'cb41bcd9-cbc1-4f2e-ac07-8dd75ebe1b64' User entered 'None (0)' | System           | 08 Sep 2020 15:51:26 |
|  | System           | 08 Sep 2020 15:51:26 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T11:51:09', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'cb41bcd9-cbc1-4f2e-ac07-8dd75ebe1b64' User entered 'None (0)' | System           | 08 Sep 2020 15:51:26 |
|  | System           | 08 Sep 2020 15:51:26 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T11:51:11', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'cb41bcd9-cbc1-4f2e-ac07-8dd75ebe1b64' User entered 'None (0)' | System           | 08 Sep 2020 15:51:26 |
|  | System           | 08 Sep 2020 15:51:26 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T11:51:12', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'cb41bcd9-cbc1-4f2e-ac07-8dd75ebe1b64' User entered 'None (0)' | System           | 08 Sep 2020 15:51:26 |
|  | System           | 08 Sep 2020 15:51:26 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T11:51:13', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'cb41bcd9-cbc1-4f2e-ac07-8dd75ebe1b64' User entered 'None (0)' | System           | 08 Sep 2020 15:51:26 |
|  | System           | 08 Sep 2020 15:51:26 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T11:51:15', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'cb41bcd9-cbc1-4f2e-ac07-8dd75ebe1b64' User entered 'None (0)' | System           | 08 Sep 2020 15:51:26 |
|  | System           | 08 Sep 2020 15:51:26 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T11:51:19', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'cb41bcd9-cbc1-4f2e-ac07-8dd75ebe1b64' User entered 'No (N)' | System           | 08 Sep 2020 15:51:26 |
|  | System           | 08 Sep 2020 15:51:26 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T11:51:22', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'cb41bcd9-cbc1-4f2e-ac07-8dd75ebe1b64' User entered '08 Sep 2020 11:51' | System           | 08 Sep 2020 15:51:26 |
|   | System           | 08 Sep 2020 15:51:26 |



US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '08 Sep 2020 11:35' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '08 Sep 2020 14:05' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.                                | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 1, after vaccination (at home)' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T19:18:53', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '70984a3f-eb31-4636-af4d-399d83e2719a' User entered 'None (0)' | System           | 08 Sep 2020 23:19:08 |
|  | System           | 08 Sep 2020 23:19:08 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T19:18:55', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '70984a3f-eb31-4636-af4d-399d83e2719a' User entered 'None (0)' | System           | 08 Sep 2020 23:19:08 |
|  | System           | 08 Sep 2020 23:19:08 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T19:18:56', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '70984a3f-eb31-4636-af4d-399d83e2719a' User entered 'None (0)' | System           | 08 Sep 2020 23:19:08 |
|  | System           | 08 Sep 2020 23:19:08 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T19:18:59', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '70984a3f-eb31-4636-af4d-399d83e2719a' User entered 'None (0)' | System           | 08 Sep 2020 23:19:08 |
|  | System           | 08 Sep 2020 23:19:08 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T19:19:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '70984a3f-eb31-4636-af4d-399d83e2719a' User entered 'None (0)' | System           | 08 Sep 2020 23:19:08 |
|  | System           | 08 Sep 2020 23:19:08 |



US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T19:19:01', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '70984a3f-eb31-4636-af4d-399d83e2719a' User entered 'None (0)' | System           | 08 Sep 2020 23:19:08 |
|  | System           | 08 Sep 2020 23:19:08 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T19:19:04', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '70984a3f-eb31-4636-af4d-399d83e2719a' User entered 'No (N)' | System           | 08 Sep 2020 23:19:08 |
|  | System           | 08 Sep 2020 23:19:08 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-08T19:19:05', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '70984a3f-eb31-4636-af4d-399d83e2719a' User entered '08 Sep 2020 19:19' | System           | 08 Sep 2020 23:19:08 |
|   | System           | 08 Sep 2020 23:19:08 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '08 Sep 2020 15:00' | System           | 08 Sep 2020 15:16:51 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '09 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 2' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-09T19:11:47', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b23b18ea-ddbf-450c-985d-b2b6b49ef7c9' User entered 'None (0)' | System           | 09 Sep 2020 23:12:01 |
|  | System           | 09 Sep 2020 23:12:01 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-09T19:11:48', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b23b18ea-ddbf-450c-985d-b2b6b49ef7c9' User entered 'None (0)' | System           | 09 Sep 2020 23:12:01 |
|  | System           | 09 Sep 2020 23:12:01 |



US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-09T19:11:50', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b23b18ea-ddbf-450c-985d-b2b6b49ef7c9' User entered 'None (0)' | System           | 09 Sep 2020 23:12:01 |
|  | System           | 09 Sep 2020 23:12:01 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-09T19:11:52', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b23b18ea-ddbf-450c-985d-b2b6b49ef7c9' User entered 'None (0)' | System           | 09 Sep 2020 23:12:01 |
|  | System           | 09 Sep 2020 23:12:01 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-09T19:11:53', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b23b18ea-ddbf-450c-985d-b2b6b49ef7c9' User entered 'None (0)' | System           | 09 Sep 2020 23:12:01 |
|  | System           | 09 Sep 2020 23:12:01 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-09T19:11:54', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b23b18ea-ddbf-450c-985d-b2b6b49ef7c9' User entered 'None (0)' | System           | 09 Sep 2020 23:12:01 |
|  | System           | 09 Sep 2020 23:12:01 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-09T19:11:56', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b23b18ea-ddbf-450c-985d-b2b6b49ef7c9' User entered 'No (N)' | System           | 09 Sep 2020 23:12:01 |
|  | System           | 09 Sep 2020 23:12:01 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-09T19:11:58', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b23b18ea-ddbf-450c-985d-b2b6b49ef7c9' User entered '09 Sep 2020 19:11' | System           | 09 Sep 2020 23:12:01 |
|   | System           | 09 Sep 2020 23:12:01 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '09 Sep 2020 12:00' | System           | 08 Sep 2020 15:16:51 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '10 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |



US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 3' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:12:07', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'af498b7b-e684-484e-b4ab-7fbbbbd830c3' | System           | 11 Sep 2020 00:12:27 |
| User entered 'No interference with activity (1)'   | System           | 11 Sep 2020 00:12:27 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:12:11', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'af498b7b-e684-484e-b4ab-7fbbbbd830c3' | System           | 11 Sep 2020 00:12:27 |
| User entered 'No interference with activity (1)'   | System           | 11 Sep 2020 00:12:27 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:12:13', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'af498b7b-e684-484e-b4ab-7fbbbbd830c3' User entered 'None (0)' | System           | 11 Sep 2020 00:12:27 |
|  | System           | 11 Sep 2020 00:12:27 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:12:14', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'af498b7b-e684-484e-b4ab-7fbbbbd830c3' User entered 'None (0)' | System           | 11 Sep 2020 00:12:27 |
|  | System           | 11 Sep 2020 00:12:27 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:12:15', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'af498b7b-e684-484e-b4ab-7fbbbbd830c3' User entered 'None (0)' | System           | 11 Sep 2020 00:12:27 |
|  | System           | 11 Sep 2020 00:12:27 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:58:29**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:12:17', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'af498b7b-e684-484e-b4ab-7fbbbbd830c3' User entered 'None (0)' | System           | 11 Sep 2020 00:12:27 |
|  | System           | 11 Sep 2020 00:12:27 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:12:21', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'af498b7b-e684-484e-b4ab-7fbbbbd830c3' | System           | 11 Sep 2020 00:12:27 |
| User entered 'No (N)'  | System           | 11 Sep 2020 00:12:27 |



**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-10T20:12:23', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'af498b7b-e684-484e-b4ab-7fbbbbd830c3' User entered '10 Sep 2020 20:12' | System           | 11 Sep 2020 00:12:27 |
|   | System           | 11 Sep 2020 00:12:27 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '10 Sep 2020 12:00' | System           | 08 Sep 2020 15:16:51 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '11 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 4' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:40:24', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c39ba069-685c-43a2-b756-f001c766b399' User entered 'None (0)' | System           | 11 Sep 2020 22:40:48 |
|  | System           | 11 Sep 2020 22:40:48 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:40:25', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c39ba069-685c-43a2-b756-f001c766b399' User entered 'None (0)' | System           | 11 Sep 2020 22:40:48 |
|  | System           | 11 Sep 2020 22:40:48 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:40:27', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c39ba069-685c-43a2-b756-f001c766b399' User entered 'None (0)' | System           | 11 Sep 2020 22:40:48 |
|  | System           | 11 Sep 2020 22:40:48 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:40:37', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c39ba069-685c-43a2-b756-f001c766b399' | System           | 11 Sep 2020 22:40:48 |
| User entered 'Some interference with activity (2)'   | System           | 11 Sep 2020 22:40:48 |



US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:40:40', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c39ba069-685c-43a2-b756-f001c766b399' User entered 'None (0)' | System           | 11 Sep 2020 22:40:48 |
|  | System           | 11 Sep 2020 22:40:48 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:40:41', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c39ba069-685c-43a2-b756-f001c766b399' User entered 'None (0)' | System           | 11 Sep 2020 22:40:48 |
|  | System           | 11 Sep 2020 22:40:48 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:40:43', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c39ba069-685c-43a2-b756-f001c766b399' | System           | 11 Sep 2020 22:40:48 |
| User entered 'No (N)'  | System           | 11 Sep 2020 22:40:48 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-11T18:40:45', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c39ba069-685c-43a2-b756-f001c766b399' User entered '11 Sep 2020 18:40' | System           | 11 Sep 2020 22:40:48 |
|   | System           | 11 Sep 2020 22:40:48 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '11 Sep 2020 12:00' | System           | 08 Sep 2020 15:16:51 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '12 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 5' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:07:48', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '4ae9f3bf-50e1-4a84-8116-d84519d4aa40' | System           | 12 Sep 2020 23:08:22 |
| User entered 'No interference with activity (1)'   | System           | 12 Sep 2020 23:08:22 |



US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:07:50', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '4ae9f3bf-50e1-4a84-8116-d84519d4aa40' | System           | 12 Sep 2020 23:08:22 |
| User entered 'Some interference with activity (2)'   | System           | 12 Sep 2020 23:08:22 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:07:57', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '4ae9f3bf-50e1-4a84-8116-d84519d4aa40' User entered 'None (0)' | System           | 12 Sep 2020 23:08:22 |
|  | System           | 12 Sep 2020 23:08:22 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:07:59', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '4ae9f3bf-50e1-4a84-8116-d84519d4aa40' | System           | 12 Sep 2020 23:08:22 |
| User entered 'No interference with activity (1)'   | System           | 12 Sep 2020 23:08:22 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:08:05', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '4ae9f3bf-50e1-4a84-8116-d84519d4aa40' User entered 'None (0)' | System           | 12 Sep 2020 23:08:22 |
|  | System           | 12 Sep 2020 23:08:22 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:08:07', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '4ae9f3bf-50e1-4a84-8116-d84519d4aa40' User entered 'None (0)' | System           | 12 Sep 2020 23:08:22 |
|  | System           | 12 Sep 2020 23:08:22 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:08:12', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '4ae9f3bf-50e1-4a84-8116-d84519d4aa40' User entered 'No (N)' | System           | 12 Sep 2020 23:08:22 |
|  | System           | 12 Sep 2020 23:08:22 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-12T19:08:14', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '4ae9f3bf-50e1-4a84-8116-d84519d4aa40' User entered '12 Sep 2020 19:08' | System           | 12 Sep 2020 23:08:22 |
|   | System           | 12 Sep 2020 23:08:22 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '12 Sep 2020 12:00' | System           | 08 Sep 2020 15:16:51 |



**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '13 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 6' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-13T19:30:59', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '20b3aaca-f3f4-4351-b372-6e8fcf873474' | System           | 13 Sep 2020 23:32:13 |
| User entered 'No interference with activity (1)'   | System           | 13 Sep 2020 23:32:13 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-13T19:31:02', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '20b3aaca-f3f4-4351-b372-6e8fcf873474' | System           | 13 Sep 2020 23:32:13 |
| User entered 'Some interference with activity (2)'   | System           | 13 Sep 2020 23:32:13 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-13T19:31:32', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '20b3aaca-f3f4-4351-b372-6e8fcf873474' User entered 'None (0)' | System           | 13 Sep 2020 23:32:13 |
|  | System           | 13 Sep 2020 23:32:13 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-13T19:31:37', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '20b3aaca-f3f4-4351-b372-6e8fcf873474' | System           | 13 Sep 2020 23:32:13 |
| User entered 'No interference with activity (1)'   | System           | 13 Sep 2020 23:32:13 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-13T19:31:44', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '20b3aaca-f3f4-4351-b372-6e8fcf873474' | System           | 13 Sep 2020 23:32:13 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'  | System           | 13 Sep 2020 23:32:13 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-13T19:31:50', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '20b3aaca-f3f4-4351-b372-6e8fcf873474' | System           | 13 Sep 2020 23:32:13 |
| User entered 'No interference with activity (1)'   | System           | 13 Sep 2020 23:32:13 |



US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-13T19:32:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '20b3aaca-f3f4-4351-b372-6e8fcf873474' User entered 'Yes (Y)' | System           | 13 Sep 2020 23:32:13 |
|   | System           | 13 Sep 2020 23:32:13 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-13T19:32:10', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '20b3aaca-f3f4-4351-b372-6e8fcf873474' User entered '13 Sep 2020 19:32' | System           | 13 Sep 2020 23:32:13 |
|   | System           | 13 Sep 2020 23:32:13 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '13 Sep 2020 12:00' | System           | 08 Sep 2020 15:16:51 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '14 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 7' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:56:42', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '162433b5-efce-4d2d-8ddf-7e9ce02e8c33' | System           | 15 Sep 2020 01:57:02 |
| User entered 'No interference with activity (1)'   | System           | 15 Sep 2020 01:57:02 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:56:44', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '162433b5-efce-4d2d-8ddf-7e9ce02e8c33' | System           | 15 Sep 2020 01:57:02 |
| User entered 'No interference with activity (1)'   | System           | 15 Sep 2020 01:57:02 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:56:47', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '162433b5-efce-4d2d-8ddf-7e9ce02e8c33' User entered 'None (0)' | System           | 15 Sep 2020 01:57:02 |
|  | System           | 15 Sep 2020 01:57:02 |



US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:56:49', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '162433b5-efce-4d2d-8ddf-7e9ce02e8c33' User entered 'None (0)' | System           | 15 Sep 2020 01:57:02 |
|  | System           | 15 Sep 2020 01:57:02 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:56:52', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '162433b5-efce-4d2d-8ddf-7e9ce02e8c33' | System           | 15 Sep 2020 01:57:02 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'  | System           | 15 Sep 2020 01:57:02 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:56:55', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '162433b5-efce-4d2d-8ddf-7e9ce02e8c33' User entered 'None (0)' | System           | 15 Sep 2020 01:57:02 |
|  | System           | 15 Sep 2020 01:57:02 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:56:59', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '162433b5-efce-4d2d-8ddf-7e9ce02e8c33' | System           | 15 Sep 2020 01:57:02 |
| User entered 'No (N)'  | System           | 15 Sep 2020 01:57:02 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-14T21:57:01', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '162433b5-efce-4d2d-8ddf-7e9ce02e8c33' | System           | 15 Sep 2020 01:57:02 |
| User entered '14 Sep 2020 21:57'   | System           | 15 Sep 2020 01:57:02 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '14 Sep 2020 12:00' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '15 Sep 2020 11:59' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 13 Sep 2020 23:32:13 |
| User entered 'Day 8' | System           | 13 Sep 2020 23:32:13 |



US3802168

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:58:29

Select one response below to indicate the intensity of your **HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-15T21:30:20', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '78670f4b-121d-43e4-adc5-2895d24be7f9' User entered 'None (0)' | System           | 16 Sep 2020 01:30:34 |
|  | System           | 16 Sep 2020 01:30:34 |

US3802168

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-15T21:30:22', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '78670f4b-121d-43e4-adc5-2895d24be7f9' | System           | 16 Sep 2020 01:30:34 |
| User entered '15 Sep 2020 21:30'   | System           | 16 Sep 2020 01:30:34 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '15 Sep 2020 12:00' | System           | 13 Sep 2020 23:32:13 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '16 Sep 2020 11:59' | System           | 13 Sep 2020 23:32:13 |

US3802168

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 13 Sep 2020 23:32:13 |
| User entered 'Day 8' | System           | 13 Sep 2020 23:32:13 |

US3802168

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 09:58:29

Select one response below to indicate the intensity of your **FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-15T21:30:25', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '538fda49-a273-4517-a569-0fbd08ccf323' User entered 'None (0)' | System           | 16 Sep 2020 01:30:33 |
|  | System           | 16 Sep 2020 01:30:33 |

US3802168

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-15T21:30:27', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '538fda49-a273-4517-a569-0fbd08ccf323' | System           | 16 Sep 2020 01:30:33 |
| User entered '15 Sep 2020 21:30'   | System           | 16 Sep 2020 01:30:33 |

US3802168

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '15 Sep 2020 12:00' | System           | 13 Sep 2020 23:32:13 |



US3802168

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '16 Sep 2020 11:59' | System           | 13 Sep 2020 23:32:13 |

US3802168

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(8)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 13 Sep 2020 23:32:13 |
| User entered 'Day 8' | System           | 13 Sep 2020 23:32:13 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 10 Jun 2021 09:58:29**

Select one response below to indicate the level of your **NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-15T21:30:29', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a1e8ed6c-ba97-4695-be55-427a18d128d6' User entered 'None (0)' | System           | 16 Sep 2020 01:30:34 |
|  | System           | 16 Sep 2020 01:30:34 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-15T21:30:30', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a1e8ed6c-ba97-4695-be55-427a18d128d6' User entered '15 Sep 2020 21:30' | System           | 16 Sep 2020 01:30:34 |
|   | System           | 16 Sep 2020 01:30:34 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '15 Sep 2020 12:00' | System           | 13 Sep 2020 23:32:13 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '16 Sep 2020 11:59' | System           | 13 Sep 2020 23:32:13 |

US3802168

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 13 Sep 2020 23:30:58 |
| User entered 'Day 8' | System           | 13 Sep 2020 23:30:58 |

US3802168

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-15T21:30:33', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '7f54fa14-bfad-4ef4-90e1-2b3c3cb5f9ee' | System           | 16 Sep 2020 01:30:39 |
| User entered 'No (N)'  | System           | 16 Sep 2020 01:30:39 |



US3802168

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:58:29

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-15T21:30:35', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '7f54fa14-bfad-4ef4-90e1-2b3c3cb5f9ee' | System           | 16 Sep 2020 01:30:39 |
| User entered '15 Sep 2020 21:30'   | System           | 16 Sep 2020 01:30:39 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '15 Sep 2020 12:00' | System           | 13 Sep 2020 23:30:58 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '16 Sep 2020 11:59' | System           | 13 Sep 2020 23:30:58 |

US3802168

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 15 Sep 2020 01:56:22 |
| User entered 'Day 9' | System           | 15 Sep 2020 01:56:22 |

US3802168

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-16T20:27:55', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'cec71fd7-7648-4c2c-bffa-fa24f0865e8d' | System           | 17 Sep 2020 00:27:59 |
| User entered 'No (N)'  | System           | 17 Sep 2020 00:27:59 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-16T20:27:57', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'cec71fd7-7648-4c2c-bffa-fa24f0865e8d' User entered '16 Sep 2020 20:27' | System           | 17 Sep 2020 00:27:59 |
|   | System           | 17 Sep 2020 00:27:59 |

US3802168

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '16 Sep 2020 12:00' | System           | 15 Sep 2020 01:56:22 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '17 Sep 2020 11:59' | System           | 15 Sep 2020 01:56:22 |



US3802168

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.    | System           | 16 Sep 2020 01:30:34 |
| User entered 'Day 10' | System           | 16 Sep 2020 01:30:34 |

US3802168

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-17T18:00:02', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '1ff0da5f-abc9-40ed-9fbe-aabeb867ee6d' User entered 'No (N)' | System           | 17 Sep 2020 22:00:08 |
|  | System           | 17 Sep 2020 22:00:08 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-17T18:00:04', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '1ff0da5f-abc9-40ed-9fbe-aabeb867ee6d' User entered '17 Sep 2020 18:00' | System           | 17 Sep 2020 22:00:08 |
|   | System           | 17 Sep 2020 22:00:08 |

US3802168

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '17 Sep 2020 12:00' | System           | 16 Sep 2020 01:30:34 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '18 Sep 2020 11:59' | System           | 16 Sep 2020 01:30:34 |

US3802168

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.    | System           | 17 Sep 2020 00:27:53 |
| User entered 'Day 11' | System           | 17 Sep 2020 00:27:53 |

US3802168

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-18T19:01:31', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '69170dc5-bdef-4d2a-8e29-4ef4587db6b8' User entered 'No (N)' | System           | 18 Sep 2020 23:01:37 |
|  | System           | 18 Sep 2020 23:01:37 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-09-18T19:01:33', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '69170dc5-bdef-4d2a-8e29-4ef4587db6b8' User entered '18 Sep 2020 19:01' | System           | 18 Sep 2020 23:01:37 |
|   | System           | 18 Sep 2020 23:01:37 |



**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '18 Sep 2020 12:00' | System           | 17 Sep 2020 00:27:53 |

**US3802168**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '19 Sep 2020 11:59' | System           | 17 Sep 2020 00:27:53 |

**US3802168**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Was Contact Attempted?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lalicia Roman (b) (4) | 16 Sep 2020 14:36:05 |

**US3802168**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:14 |
| User entered '16 Sep 2020' | (b) (4)<br>Lalicia Roman (b) (4) | 16 Sep 2020 14:36:05 |

**US3802168**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded.                  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:14 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Lalicia Roman (b) (4) | 16 Sep 2020 14:36:05 |

**US3802168**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered empty.       | Lalicia Roman (b) (4)<br>(b) (4) | 16 Sep 2020 14:36:05 |

US3802168

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:29

[Is the participant continuing to the next visit?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lalicia Roman (b) (4) | 16 Sep 2020 14:36:09 |

**US3802168**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'I'  | System           | 16 Sep 2020 14:36:09 |



**US3802168**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Was Contact Attempted?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lalicia Roman (b) (4) | 23 Sep 2020 18:37:08 |

**US3802168**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '23 Sep 2020' | (b) (4)<br>Lalicia Roman (b) (4) | 23 Sep 2020 18:37:08 |

**US3802168**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded.                  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Lalicia Roman (b) (4) | 23 Sep 2020 18:37:08 |

US3802168

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:29

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Lalicia Roman (b) (4) | 23 Sep 2020 18:37:08 |

**US3802168**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lalicia Roman (b) (4) | 23 Sep 2020 18:37:12 |

**US3802168**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'I'  | System           | 23 Sep 2020 18:37:12 |

**US3802168**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Was Contact Attempted?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lalicia Roman (b) (4) | 30 Sep 2020 17:56:40 |

**US3802168**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 27 Mar 2021 12:17:58 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered '30 Sep 2020' | (b) (4)<br>Lalicia Roman (b) (4)<br>(b) (4) | 30 Sep 2020 17:56:40 |



**US3802168**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded.                  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Lalicia Roman (b) (4) | 30 Sep 2020 17:56:40 |

**US3802168**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:07 |
| User entered empty.       | Lalicia Roman (b) (4)<br>(b) (4) | 30 Sep 2020 17:56:40 |

**US3802168**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lalicia Roman (b) (4) | 30 Sep 2020 17:56:43 |

**US3802168**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'I'  | System           | 30 Sep 2020 17:56:43 |

**US3802168**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Was this visit performed?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:05:24 |

**US3802168**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '9 Oct 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:05:24 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:29

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                                       | Time (GMT)           |
|--------------------------------|--|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded.      | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:05:24 |

**US3802168**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'VISIT2' | System           | 09 Oct 2020 17:05:24 |



US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Timepoint](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)                | 27 Mar 2021 12:19:09 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Were vital signs assessed?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '9 Oct 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

Time of assessment (00:00-23:59)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '12:56'      | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
| User entered '9 Oct 2020 12:56' | System           | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

Temperature (xxx.x)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '98.6' F     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Route of measurement](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                 | 27 Mar 2021 12:19:09 |
| User signature succeeded.    | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered 'Other (Other)' | Emily Carney (b) (4)<br>(b) (4)  | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[If Other, specify](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'Infrared'   | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:55:07 |



**US3802168**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Pulse \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered '76'         | Emily Carney (b) (4)<br>(b) (4)  | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
| User entered 'bpm' | System           | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '18'         | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
| User entered 'breaths/min' | System           | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered '138'        | Emily Carney (b) (4)<br>(b) (4)  | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
| User entered 'mmHg' | System           | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered '86'         | Emily Carney (b) (4)<br>(b) (4)  | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
| User entered 'mmHg' | System           | 09 Oct 2020 17:55:07 |



US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Timepoint](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                | 27 Mar 2021 12:19:09 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Were vital signs assessed?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '9 Oct 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

Time of assessment (00:00-23:59)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '13:48'      | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
| User entered '9 Oct 2020 13:48' | System           | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

Temperature (xxx.x)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '98.1' F     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Route of measurement](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                 | 27 Mar 2021 12:19:09 |
| User signature succeeded.    | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered 'Other (Other)' | Emily Carney (b) (4)<br>(b) (4)  | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[If Other, specify](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'Infrared'   | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:55:07 |



US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Pulse \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered '76'         | Emily Carney (b) (4)<br>(b) (4)  | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
| User entered 'bpm' | System           | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered '18'         | Emily Carney (b) (4)<br>(b) (4)  | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
| User entered 'breaths/min' | System           | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

Systolic Blood Pressure (xxx)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered '137'        | Emily Carney (b) (4)<br>(b) (4)  | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
| User entered 'mmHg' | System           | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered '86'         | Emily Carney (b) (4)<br>(b) (4)  | 09 Oct 2020 17:55:07 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
| User entered 'mmHg' | System           | 09 Oct 2020 17:55:07 |



**US3802168**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:58:29**

[Was the physical examination performed?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:11:25 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:29

Date of examination (*dd MMM yyyy*)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:11:25 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

[Was study treatment given?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:23:55 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

[If No, reason not given](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:23:55 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered empty.       | Emily Carney (b) (4)<br>(b) (4)  | 09 Oct 2020 17:23:55 |

**US3802168**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:58:29**

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

What was the treatment date? (dd MMM yyyy)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '9 Oct 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:23:55 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '13:18'      | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:23:55 |



US3802168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

[Treatment Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered '9 Oct 2020 13:18' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

[Which arm was used to give treatment?](#)

| Audit                              | User                             | Time (GMT)           |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded.          | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered 'Left Arm (LEFT ARM)' | Emily Carney (b) (4)<br>(b) (4)  | 09 Oct 2020 17:23:55 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'ONCE' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'INTRAMUSCULAR' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:29

[Was the sample collected?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:11:48 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:29

Collection date (*dd MMM yyyy*)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '9 Oct 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:11:48 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:29

Collection time (00:00-23:59)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered '13:08'      | Emily Carney (b) (4)<br>(b) (4)  | 09 Oct 2020 17:11:48 |

**US3802168**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:58:29**

[Collection date and time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered '9 Oct 2020 13:08' | System           | 09 Oct 2020 17:11:48 |



US3802168

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:58:29

Collection date (*dd MMM yyyy*)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '9 Oct 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:12:04 |

**US3802168**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Lab Test](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 27 Mar 2021 12:17:58 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:12:04 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:29

[Was the sample collected?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)           | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 09 Oct 2020 17:12:04 |

**US3802168**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '13:09'      | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:12:04 |

**US3802168**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Collection date and time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered '9 Oct 2020 13:09' | System           | 09 Oct 2020 17:12:04 |

**US3802168**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Lab Test](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 27 Mar 2021 12:17:58 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:12:04 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:29

[Was the sample collected?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:12:04 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:29

Collection time (00:00 - 23:59)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:12:04 |



**US3802168**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered empty. | System           | 09 Oct 2020 17:12:04 |

US3802168

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:29

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Oct 2020 17:12:08 |

**US3802168**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered '1'  | System           | 09 Oct 2020 17:12:08 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T13:51:17', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'db1abd0f-f1f1-4b93-96b1-af522c07aef7' | System           | 09 Oct 2020 17:51:56 |
| User entered 'Yes (Y)'   | System           | 09 Oct 2020 17:51:56 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T13:51:21', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'db1abd0f-f1f1-4b93-96b1-af522c07aef7' | System           | 09 Oct 2020 17:51:56 |
| User entered '98.1'  | System           | 09 Oct 2020 17:51:56 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T13:51:24', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'db1abd0f-f1f1-4b93-96b1-af522c07aef7' | System           | 09 Oct 2020 17:51:56 |
| User entered 'No (N)'  | System           | 09 Oct 2020 17:51:56 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T13:51:54', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'db1abd0f-f1f1-4b93-96b1-af522c07aef7' User entered '09 Oct 2020 13:51' | System           | 09 Oct 2020 17:51:56 |
|   | System           | 09 Oct 2020 17:51:56 |



US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '09 Oct 2020 13:38' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '09 Oct 2020 16:08' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.                                | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 1, after vaccination (at home)' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T19:46:17', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '9b6fc710-a1de-4bdf-8f2e-21f1d9343397' | System           | 09 Oct 2020 23:46:30 |
| User entered 'Yes (Y)'   | System           | 09 Oct 2020 23:46:30 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T19:46:24', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '9b6fc710-a1de-4bdf-8f2e-21f1d9343397' | System           | 09 Oct 2020 23:46:30 |
| User entered '98.1'  | System           | 09 Oct 2020 23:46:30 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T19:46:26', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '9b6fc710-a1de-4bdf-8f2e-21f1d9343397' | System           | 09 Oct 2020 23:46:30 |
| User entered 'No (N)'  | System           | 09 Oct 2020 23:46:30 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T19:46:28', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '9b6fc710-a1de-4bdf-8f2e-21f1d9343397' | System           | 09 Oct 2020 23:46:30 |
| User entered '09 Oct 2020 19:46'   | System           | 09 Oct 2020 23:46:30 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '09 Oct 2020 17:03' | System           | 09 Oct 2020 17:23:55 |



US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '10 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 2' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-10T19:46:11', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '505cb252-369f-4118-a390-952558aef8e7' User entered 'Yes (Y)' | System           | 10 Oct 2020 23:46:23 |
|   | System           | 10 Oct 2020 23:46:23 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-10T19:46:15', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '505cb252-369f-4118-a390-952558aef8e7' User entered '97.9' | System           | 10 Oct 2020 23:46:23 |
|  | System           | 10 Oct 2020 23:46:23 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-10T19:46:18', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '505cb252-369f-4118-a390-952558aef8e7' | System           | 10 Oct 2020 23:46:23 |
| User entered 'No (N)'  | System           | 10 Oct 2020 23:46:23 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-10T19:46:20', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '505cb252-369f-4118-a390-952558aef8e7' User entered '10 Oct 2020 19:46' | System           | 10 Oct 2020 23:46:23 |
|   | System           | 10 Oct 2020 23:46:23 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '10 Oct 2020 12:00' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '11 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |



US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 3' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:24:54', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a0a95485-d4bc-4fa6-a8de-44e8cd180a90' User entered 'Yes (Y)' | System           | 12 Oct 2020 00:28:55 |
|   | System           | 12 Oct 2020 00:28:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:24:59', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a0a95485-d4bc-4fa6-a8de-44e8cd180a90' User entered '97.9' | System           | 12 Oct 2020 00:28:55 |
|  | System           | 12 Oct 2020 00:28:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:25:01', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a0a95485-d4bc-4fa6-a8de-44e8cd180a90' | System           | 12 Oct 2020 00:28:55 |
| User entered 'Yes (Y)'   | System           | 12 Oct 2020 00:28:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

To **TREAT** pain or fever that has already occurred

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 06 Mar 2021 23:22:52 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant did not indicate during his day 36 safety call that he took any medication for pain or fever' (Site from System). | (b) (4)               | 19 Nov 2020 14:55:53 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).   | Lalicia Roman (b) (4) | 30 Oct 2020 20:21:21 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:25:05', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a0a95485-d4bc-4fa6-a8de-44e8cd180a90'   | System                | 12 Oct 2020 00:28:55 |
| User entered '1'   | System                | 12 Oct 2020 00:28:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:25:05', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a0a95485-d4bc-4fa6-a8de-44e8cd180a90' User entered '0' | System           | 12 Oct 2020 00:28:55 |
|   | System           | 12 Oct 2020 00:28:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:25:08', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a0a95485-d4bc-4fa6-a8de-44e8cd180a90' | System           | 12 Oct 2020 00:28:55 |
| User entered '11 Oct 2020 20:25'   | System           | 12 Oct 2020 00:28:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '11 Oct 2020 12:00' | System           | 09 Oct 2020 17:23:55 |



US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '12 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 4' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:34:31', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '29ef4390-9ff9-4c31-b6b1-aeba0f659faf' | System           | 12 Oct 2020 22:34:45 |
| User entered 'Yes (Y)'   | System           | 12 Oct 2020 22:34:45 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:34:34', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '29ef4390-9ff9-4c31-b6b1-aeba0f659faf' User entered '97.5' | System           | 12 Oct 2020 22:34:45 |
|  | System           | 12 Oct 2020 22:34:45 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:34:37', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '29ef4390-9ff9-4c31-b6b1-aeba0f659faf' | System           | 12 Oct 2020 22:34:45 |
| User entered 'Yes (Y)'   | System           | 12 Oct 2020 22:34:45 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

To **TREAT** pain or fever that has already occurred

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 06 Mar 2021 23:22:52 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant did not indicate during his day 36 safety call that he took any medication for pain or fever' (Site from System). | (b) (4), (b) (6)      | 19 Nov 2020 14:56:08 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).   | Lalicia Roman (b) (4) | 30 Oct 2020 20:21:26 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:34:40', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '29ef4390-9ff9-4c31-b6b1-aeba0f659faf'   | (b) (4)               |                      |
| User entered '1'   | System                | 12 Oct 2020 22:34:45 |
|  | System                | 12 Oct 2020 22:34:45 |
|  | System                | 12 Oct 2020 22:34:45 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

To **PREVENT** pain or fever from occurring

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:34:40', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '29ef4390-9ff9-4c31-b6b1-aeba0f659faf' | System           | 12 Oct 2020 22:34:45 |
| User entered '0'   | System           | 12 Oct 2020 22:34:45 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:34:43', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '29ef4390-9ff9-4c31-b6b1-aeba0f659faf' | System           | 12 Oct 2020 22:34:45 |
| User entered '12 Oct 2020 18:34'   | System           | 12 Oct 2020 22:34:45 |



US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '12 Oct 2020 12:00' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '13 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 5' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-13T20:16:26', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '393f5b6c-4b5f-4913-b3b3-e1dbcbadf0d0' User entered 'Yes (Y)' | System           | 14 Oct 2020 00:16:39 |
|   | System           | 14 Oct 2020 00:16:39 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-13T20:16:29', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '393f5b6c-4b5f-4913-b3b3-e1dbcbadf0d0' User entered '97.5' | System           | 14 Oct 2020 00:16:39 |
|  | System           | 14 Oct 2020 00:16:39 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-13T20:16:33', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '393f5b6c-4b5f-4913-b3b3-e1dbcbadf0d0' | System           | 14 Oct 2020 00:16:39 |
| User entered 'No (N)'  | System           | 14 Oct 2020 00:16:39 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-13T20:16:35', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '393f5b6c-4b5f-4913-b3b3-e1dbcbadf0d0' User entered '13 Oct 2020 20:16' | System           | 14 Oct 2020 00:16:39 |
|   | System           | 14 Oct 2020 00:16:39 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '13 Oct 2020 12:00' | System           | 09 Oct 2020 17:23:55 |



US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '14 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 6' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T05:20:37', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'ce788eb7-92aa-4d07-9b6b-cb33ba8214ff' User entered 'Yes (Y)' | System           | 15 Oct 2020 09:20:47 |
|   | System           | 15 Oct 2020 09:20:47 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T05:20:41', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'ce788eb7-92aa-4d07-9b6b-cb33ba8214ff' User entered '97.7' | System           | 15 Oct 2020 09:20:47 |
|  | System           | 15 Oct 2020 09:20:47 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T05:20:43', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'ce788eb7-92aa-4d07-9b6b-cb33ba8214ff' User entered 'No (N)' | System           | 15 Oct 2020 09:20:47 |
|  | System           | 15 Oct 2020 09:20:47 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T05:20:45', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'ce788eb7-92aa-4d07-9b6b-cb33ba8214ff' User entered '15 Oct 2020 05:20' | System           | 15 Oct 2020 09:20:47 |
|   | System           | 15 Oct 2020 09:20:47 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '14 Oct 2020 12:00' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '15 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |



US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 7' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:29

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T21:07:29', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a3def090-76c8-4e89-ad13-3ae89be1a51d' User entered 'Yes (Y)' | System           | 16 Oct 2020 01:07:41 |
|   | System           | 16 Oct 2020 01:07:41 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:29

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T21:07:34', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a3def090-76c8-4e89-ad13-3ae89be1a51d' User entered '97.9' | System           | 16 Oct 2020 01:07:41 |
|  | System           | 16 Oct 2020 01:07:41 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T21:07:36', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a3def090-76c8-4e89-ad13-3ae89be1a51d' User entered 'No (N)' | System           | 16 Oct 2020 01:07:41 |
|  | System           | 16 Oct 2020 01:07:41 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T21:07:38', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a3def090-76c8-4e89-ad13-3ae89be1a51d' User entered '15 Oct 2020 21:07' | System           | 16 Oct 2020 01:07:41 |
|   | System           | 16 Oct 2020 01:07:41 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '15 Oct 2020 12:00' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '16 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 09 Oct 2020 17:23:55 |



US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T13:51:57', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '991d4d9e-18b0-47f2-9dfa-a0ec974c4557' | System           | 09 Oct 2020 17:52:08 |
| User entered 'None (1)'  | System           | 09 Oct 2020 17:52:08 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T13:51:59', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '991d4d9e-18b0-47f2-9dfa-a0ec974c4557' | System           | 09 Oct 2020 17:52:08 |
| User entered 'No (N)'  | System           | 09 Oct 2020 17:52:08 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T13:52:01', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '991d4d9e-18b0-47f2-9dfa-a0ec974c4557' | System           | 09 Oct 2020 17:52:08 |
| User entered 'No (N)'  | System           | 09 Oct 2020 17:52:08 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T13:52:03', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '991d4d9e-18b0-47f2-9dfa-a0ec974c4557' | System           | 09 Oct 2020 17:52:08 |
| User entered 'None (1)'  | System           | 09 Oct 2020 17:52:08 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T13:52:06', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '991d4d9e-18b0-47f2-9dfa-a0ec974c4557' User entered '09 Oct 2020 13:52' | System           | 09 Oct 2020 17:52:08 |
|   | System           | 09 Oct 2020 17:52:08 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '09 Oct 2020 13:38' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '09 Oct 2020 16:08' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.                                | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 1, after vaccination (at home)' | System           | 09 Oct 2020 17:23:55 |



US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T19:46:37', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '4630aee2-bd34-46cf-88df-4d3e18f1c6f9' | System           | 09 Oct 2020 23:46:50 |
| User entered 'Does not interfere with activity (2)'  | System           | 09 Oct 2020 23:46:50 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T19:46:39', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '4630aee2-bd34-46cf-88df-4d3e18f1c6f9' | System           | 09 Oct 2020 23:46:50 |
| User entered 'No (N)'  | System           | 09 Oct 2020 23:46:50 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T19:46:41', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '4630aee2-bd34-46cf-88df-4d3e18f1c6f9' User entered 'No (N)' | System           | 09 Oct 2020 23:46:50 |
|  | System           | 09 Oct 2020 23:46:50 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T19:46:43', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '4630aee2-bd34-46cf-88df-4d3e18f1c6f9' | System           | 09 Oct 2020 23:46:50 |
| User entered 'None (1)'  | System           | 09 Oct 2020 23:46:50 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T19:46:46', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '4630aee2-bd34-46cf-88df-4d3e18f1c6f9' User entered '09 Oct 2020 19:46' | System           | 09 Oct 2020 23:46:50 |
|   | System           | 09 Oct 2020 23:46:50 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '09 Oct 2020 17:03' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '10 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 2' | System           | 09 Oct 2020 17:23:55 |



US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-10T19:46:28', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '5ad143d5-4d78-430b-9ee2-a8fac9e49866' | System           | 10 Oct 2020 23:47:12 |
| User entered 'Does not interfere with activity (2)'  | System           | 10 Oct 2020 23:47:12 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:29

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-10T19:46:36', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '5ad143d5-4d78-430b-9ee2-a8fac9e49866' | System           | 10 Oct 2020 23:47:12 |
| User entered 'No (N)'  | System           | 10 Oct 2020 23:47:12 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-10T19:46:42', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '5ad143d5-4d78-430b-9ee2-a8fac9e49866' | System           | 10 Oct 2020 23:47:12 |
| User entered 'No (N)'  | System           | 10 Oct 2020 23:47:12 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-10T19:47:04', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '5ad143d5-4d78-430b-9ee2-a8fac9e49866' | System           | 10 Oct 2020 23:47:12 |
| User entered 'Does not interfere with activity (2)'  | System           | 10 Oct 2020 23:47:12 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-10T19:47:07', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '5ad143d5-4d78-430b-9ee2-a8fac9e49866' User entered '10 Oct 2020 19:47' | System           | 10 Oct 2020 23:47:12 |
|   | System           | 10 Oct 2020 23:47:12 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '10 Oct 2020 12:00' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '11 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 3' | System           | 09 Oct 2020 17:23:55 |



US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:25:13', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e1b021fe-91d9-42c6-a491-51b90b9da978' | System           | 12 Oct 2020 00:28:57 |
| User entered 'Does not interfere with activity (2)'  | System           | 12 Oct 2020 00:28:57 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:29

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:25:16', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e1b021fe-91d9-42c6-a491-51b90b9da978' User entered 'No (N)' | System           | 12 Oct 2020 00:28:57 |
|  | System           | 12 Oct 2020 00:28:57 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:25:17', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e1b021fe-91d9-42c6-a491-51b90b9da978' User entered 'No (N)' | System           | 12 Oct 2020 00:28:57 |
|  | System           | 12 Oct 2020 00:28:57 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:25:19', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e1b021fe-91d9-42c6-a491-51b90b9da978' User entered 'None (1)' | System           | 12 Oct 2020 00:28:57 |
|  | System           | 12 Oct 2020 00:28:57 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:25:21', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e1b021fe-91d9-42c6-a491-51b90b9da978' | System           | 12 Oct 2020 00:28:57 |
| User entered '11 Oct 2020 20:25'   | System           | 12 Oct 2020 00:28:57 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '11 Oct 2020 12:00' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '12 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 4' | System           | 09 Oct 2020 17:23:55 |



US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:34:46', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2b9dda2b-9c97-4bee-9877-878cbf2dc530' | System           | 12 Oct 2020 22:34:56 |
| User entered 'Does not interfere with activity (2)'  | System           | 12 Oct 2020 22:34:56 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:29

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:34:48', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2b9dda2b-9c97-4bee-9877-878cbf2dc530' User entered 'No (N)' | System           | 12 Oct 2020 22:34:56 |
|  | System           | 12 Oct 2020 22:34:56 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:34:50', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2b9dda2b-9c97-4bee-9877-878cbf2dc530' User entered 'No (N)' | System           | 12 Oct 2020 22:34:56 |
|  | System           | 12 Oct 2020 22:34:56 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:34:53', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2b9dda2b-9c97-4bee-9877-878cbf2dc530' | System           | 12 Oct 2020 22:34:56 |
| User entered 'Does not interfere with activity (2)'  | System           | 12 Oct 2020 22:34:56 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:34:55', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2b9dda2b-9c97-4bee-9877-878cbf2dc530' | System           | 12 Oct 2020 22:34:56 |
| User entered '12 Oct 2020 18:34'   | System           | 12 Oct 2020 22:34:56 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '12 Oct 2020 12:00' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '13 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 5' | System           | 09 Oct 2020 17:23:55 |



US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-13T20:16:40', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2a6f6fa0-7afc-4cb0-824b-458495cb256f' User entered 'Does not interfere with activity (2)' | System           | 14 Oct 2020 00:16:55 |
|  | System           | 14 Oct 2020 00:16:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:29

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-13T20:16:45', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2a6f6fa0-7afc-4cb0-824b-458495cb256f' User entered 'No (N)' | System           | 14 Oct 2020 00:16:55 |
|  | System           | 14 Oct 2020 00:16:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-13T20:16:47', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2a6f6fa0-7afc-4cb0-824b-458495cb256f' User entered 'No (N)' | System           | 14 Oct 2020 00:16:55 |
|  | System           | 14 Oct 2020 00:16:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-13T20:16:48', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2a6f6fa0-7afc-4cb0-824b-458495cb256f' User entered 'None (1)' | System           | 14 Oct 2020 00:16:55 |
|  | System           | 14 Oct 2020 00:16:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:29

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-13T20:16:50', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2a6f6fa0-7afc-4cb0-824b-458495cb256f' User entered '13 Oct 2020 20:16' | System           | 14 Oct 2020 00:16:55 |
|   | System           | 14 Oct 2020 00:16:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '13 Oct 2020 12:00' | System           | 09 Oct 2020 17:23:55 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '14 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 6' | System           | 09 Oct 2020 17:23:55 |



US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T05:20:51', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a694cf39-d0f9-497c-bdd5-6f45e3765dd9' | System           | 15 Oct 2020 09:21:04 |
| User entered 'Does not interfere with activity (2)'  | System           | 15 Oct 2020 09:21:04 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:29

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T05:20:53', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a694cf39-d0f9-497c-bdd5-6f45e3765dd9' User entered 'No (N)' | System           | 15 Oct 2020 09:21:04 |
|  | System           | 15 Oct 2020 09:21:04 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T05:20:54', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a694cf39-d0f9-497c-bdd5-6f45e3765dd9' User entered 'No (N)' | System           | 15 Oct 2020 09:21:04 |
|  | System           | 15 Oct 2020 09:21:04 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T05:20:56', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a694cf39-d0f9-497c-bdd5-6f45e3765dd9' | System           | 15 Oct 2020 09:21:04 |
| User entered 'Does not interfere with activity (2)'  | System           | 15 Oct 2020 09:21:04 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T05:20:58', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a694cf39-d0f9-497c-bdd5-6f45e3765dd9' User entered '15 Oct 2020 05:20' | System           | 15 Oct 2020 09:21:04 |
|   | System           | 15 Oct 2020 09:21:04 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '14 Oct 2020 12:00' | System           | 09 Oct 2020 17:23:55 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '15 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 7' | System           | 09 Oct 2020 17:23:55 |



US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T21:07:43', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '5e94d921-ce12-45f0-8af7-b24ba4c54b15' User entered 'None (1)' | System           | 16 Oct 2020 01:07:55 |
|  | System           | 16 Oct 2020 01:07:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:29

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T21:07:44', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '5e94d921-ce12-45f0-8af7-b24ba4c54b15' User entered 'No (N)' | System           | 16 Oct 2020 01:07:55 |
|  | System           | 16 Oct 2020 01:07:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T21:07:47', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '5e94d921-ce12-45f0-8af7-b24ba4c54b15' User entered 'No (N)' | System           | 16 Oct 2020 01:07:55 |
|  | System           | 16 Oct 2020 01:07:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T21:07:48', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '5e94d921-ce12-45f0-8af7-b24ba4c54b15' | System           | 16 Oct 2020 01:07:55 |
| User entered 'Does not interfere with activity (2)'  | System           | 16 Oct 2020 01:07:55 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T21:07:50', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '5e94d921-ce12-45f0-8af7-b24ba4c54b15' User entered '15 Oct 2020 21:07' | System           | 16 Oct 2020 01:07:55 |
|   | System           | 16 Oct 2020 01:07:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '15 Oct 2020 12:00' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '16 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 09 Oct 2020 17:23:55 |



US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T13:54:04', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '61cb364a-abf1-464a-a140-4a5a55e17bba' User entered 'None (0)' | System           | 09 Oct 2020 17:55:57 |
|  | System           | 09 Oct 2020 17:55:57 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T13:54:05', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '61cb364a-abf1-464a-a140-4a5a55e17bba' User entered 'None (0)' | System           | 09 Oct 2020 17:55:57 |
|  | System           | 09 Oct 2020 17:55:57 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T13:54:06', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '61cb364a-abf1-464a-a140-4a5a55e17bba' User entered 'None (0)' | System           | 09 Oct 2020 17:55:57 |
|  | System           | 09 Oct 2020 17:55:57 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T13:54:07', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '61cb364a-abf1-464a-a140-4a5a55e17bba' User entered 'None (0)' | System           | 09 Oct 2020 17:55:57 |
|  | System           | 09 Oct 2020 17:55:57 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T13:54:23', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '61cb364a-abf1-464a-a140-4a5a55e17bba' User entered 'None (0)' | System           | 09 Oct 2020 17:55:57 |
|  | System           | 09 Oct 2020 17:55:57 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T13:55:51', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '61cb364a-abf1-464a-a140-4a5a55e17bba' User entered 'None (0)' | System           | 09 Oct 2020 17:55:57 |
|  | System           | 09 Oct 2020 17:55:57 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T13:55:53', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '61cb364a-abf1-464a-a140-4a5a55e17bba' User entered 'No (N)' | System           | 09 Oct 2020 17:55:57 |
|  | System           | 09 Oct 2020 17:55:57 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T13:55:55', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '61cb364a-abf1-464a-a140-4a5a55e17bba' User entered '09 Oct 2020 13:55' | System           | 09 Oct 2020 17:55:57 |
|   | System           | 09 Oct 2020 17:55:57 |



US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '09 Oct 2020 13:38' | System           | 09 Oct 2020 17:23:55 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '09 Oct 2020 16:08' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.                                | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 1, after vaccination (at home)' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T19:46:51', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '344e7a2d-7fc6-437e-888b-f477b8a6ead0' | System           | 09 Oct 2020 23:47:07 |
| User entered 'No interference with activity (1)'   | System           | 09 Oct 2020 23:47:07 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T19:46:53', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '344e7a2d-7fc6-437e-888b-f477b8a6ead0' User entered 'None (0)' | System           | 09 Oct 2020 23:47:07 |
|  | System           | 09 Oct 2020 23:47:07 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T19:46:55', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '344e7a2d-7fc6-437e-888b-f477b8a6ead0' User entered 'None (0)' | System           | 09 Oct 2020 23:47:07 |
|  | System           | 09 Oct 2020 23:47:07 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T19:46:56', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '344e7a2d-7fc6-437e-888b-f477b8a6ead0' User entered 'None (0)' | System           | 09 Oct 2020 23:47:07 |
|  | System           | 09 Oct 2020 23:47:07 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T19:46:58', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '344e7a2d-7fc6-437e-888b-f477b8a6ead0' User entered 'None (0)' | System           | 09 Oct 2020 23:47:07 |
|  | System           | 09 Oct 2020 23:47:07 |



US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T19:46:59', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '344e7a2d-7fc6-437e-888b-f477b8a6ead0' User entered 'None (0)' | System           | 09 Oct 2020 23:47:07 |
|  | System           | 09 Oct 2020 23:47:07 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T19:47:02', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '344e7a2d-7fc6-437e-888b-f477b8a6ead0' User entered 'No (N)' | System           | 09 Oct 2020 23:47:07 |
|  | System           | 09 Oct 2020 23:47:07 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-09T19:47:04', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '344e7a2d-7fc6-437e-888b-f477b8a6ead0' User entered '09 Oct 2020 19:47' | System           | 09 Oct 2020 23:47:07 |
|   | System           | 09 Oct 2020 23:47:07 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '09 Oct 2020 17:03' | System           | 09 Oct 2020 17:23:55 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '10 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 2' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-10T19:47:23', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '1a6e7016-3b7b-4e81-ad11-4c55119adffb' User entered 'None (0)' | System           | 10 Oct 2020 23:47:44 |
|  | System           | 10 Oct 2020 23:47:44 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**FATIGUE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-10T19:47:25', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '1a6e7016-3b7b-4e81-ad11-4c55119adffb' User entered 'Some interference with activity (2)' | System           | 10 Oct 2020 23:47:44 |
|   | System           | 10 Oct 2020 23:47:44 |



US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-10T19:47:28', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '1a6e7016-3b7b-4e81-ad11-4c55119adffb' User entered 'None (0)' | System           | 10 Oct 2020 23:47:44 |
|  | System           | 10 Oct 2020 23:47:44 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-10T19:47:30', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '1a6e7016-3b7b-4e81-ad11-4c55119adffb' User entered 'None (0)' | System           | 10 Oct 2020 23:47:44 |
|  | System           | 10 Oct 2020 23:47:44 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-10T19:47:32', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '1a6e7016-3b7b-4e81-ad11-4c55119adffb' User entered 'None (0)' | System           | 10 Oct 2020 23:47:44 |
|  | System           | 10 Oct 2020 23:47:44 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-10T19:47:33', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '1a6e7016-3b7b-4e81-ad11-4c55119adffb' User entered 'None (0)' | System           | 10 Oct 2020 23:47:44 |
|  | System           | 10 Oct 2020 23:47:44 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-10T19:47:38', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '1a6e7016-3b7b-4e81-ad11-4c55119adffb' User entered 'No (N)' | System           | 10 Oct 2020 23:47:44 |
|  | System           | 10 Oct 2020 23:47:44 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-10T19:47:40', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '1a6e7016-3b7b-4e81-ad11-4c55119adffb' User entered '10 Oct 2020 19:47' | System           | 10 Oct 2020 23:47:44 |
|   | System           | 10 Oct 2020 23:47:44 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '10 Oct 2020 12:00' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:29

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '11 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |



US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 3' | System           | 09 Oct 2020 17:23:55 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:58:29**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:25:31', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '269aa5c6-1404-4c73-8bd8-fd00ded7425b' | System           | 12 Oct 2020 00:29:00 |
| User entered 'No interference with activity (1)'   | System           | 12 Oct 2020 00:29:00 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:58:29**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:25:34', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '269aa5c6-1404-4c73-8bd8-fd00ded7425b' | System           | 12 Oct 2020 00:29:00 |
| User entered 'Some interference with activity (2)'   | System           | 12 Oct 2020 00:29:00 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:25:38', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '269aa5c6-1404-4c73-8bd8-fd00ded7425b' User entered 'None (0)' | System           | 12 Oct 2020 00:29:00 |
|  | System           | 12 Oct 2020 00:29:00 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:25:40', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '269aa5c6-1404-4c73-8bd8-fd00ded7425b' User entered 'None (0)' | System           | 12 Oct 2020 00:29:00 |
|  | System           | 12 Oct 2020 00:29:00 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:25:42', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '269aa5c6-1404-4c73-8bd8-fd00ded7425b' | System           | 12 Oct 2020 00:29:00 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'  | System           | 12 Oct 2020 00:29:00 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:25:45', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '269aa5c6-1404-4c73-8bd8-fd00ded7425b' User entered 'None (0)' | System           | 12 Oct 2020 00:29:00 |
|  | System           | 12 Oct 2020 00:29:00 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:25:46', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '269aa5c6-1404-4c73-8bd8-fd00ded7425b' User entered 'No (N)' | System           | 12 Oct 2020 00:29:00 |
|  | System           | 12 Oct 2020 00:29:00 |



**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-11T20:25:48', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '269aa5c6-1404-4c73-8bd8-fd00ded7425b' User entered '11 Oct 2020 20:25' | System           | 12 Oct 2020 00:29:00 |
|   | System           | 12 Oct 2020 00:29:00 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '11 Oct 2020 12:00' | System           | 09 Oct 2020 17:23:55 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '12 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 4' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:34:58', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '63424962-17f5-40f9-859a-8a8399b971e2' | System           | 12 Oct 2020 22:35:27 |
| User entered 'No interference with activity (1)'   | System           | 12 Oct 2020 22:35:27 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:35:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '63424962-17f5-40f9-859a-8a8399b971e2' | System           | 12 Oct 2020 22:35:27 |
| User entered 'Some interference with activity (2)'   | System           | 12 Oct 2020 22:35:27 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:35:04', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '63424962-17f5-40f9-859a-8a8399b971e2' | System           | 12 Oct 2020 22:35:27 |
| User entered 'No interference with activity (1)'   | System           | 12 Oct 2020 22:35:27 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:35:06', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '63424962-17f5-40f9-859a-8a8399b971e2' User entered 'None (0)' | System           | 12 Oct 2020 22:35:27 |
|  | System           | 12 Oct 2020 22:35:27 |



US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:35:09', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '63424962-17f5-40f9-859a-8a8399b971e2' User entered 'None (0)' | System           | 12 Oct 2020 22:35:27 |
|  | System           | 12 Oct 2020 22:35:27 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:58:29**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:35:11', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '63424962-17f5-40f9-859a-8a8399b971e2' | System           | 12 Oct 2020 22:35:27 |
| User entered 'No interference with activity (1)'   | System           | 12 Oct 2020 22:35:27 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:35:13', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '63424962-17f5-40f9-859a-8a8399b971e2' User entered 'No (N)' | System           | 12 Oct 2020 22:35:27 |
|  | System           | 12 Oct 2020 22:35:27 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-12T18:35:14', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '63424962-17f5-40f9-859a-8a8399b971e2' User entered '12 Oct 2020 18:35' | System           | 12 Oct 2020 22:35:27 |
|   | System           | 12 Oct 2020 22:35:27 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '12 Oct 2020 12:00' | System           | 09 Oct 2020 17:23:55 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '13 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 5' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-13T20:16:54', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'd8bc3cc7-5317-40a9-9c48-cddceb4087c6' | System           | 14 Oct 2020 00:17:12 |
| User entered 'No interference with activity (1)'   | System           | 14 Oct 2020 00:17:12 |



US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-13T20:16:57', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'd8bc3cc7-5317-40a9-9c48-cddceb4087c6' | System           | 14 Oct 2020 00:17:12 |
| User entered 'No interference with activity (1)'   | System           | 14 Oct 2020 00:17:12 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-13T20:16:59', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'd8bc3cc7-5317-40a9-9c48-cddceb4087c6' | System           | 14 Oct 2020 00:17:12 |
| User entered 'No interference with activity (1)'   | System           | 14 Oct 2020 00:17:12 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-13T20:17:02', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'd8bc3cc7-5317-40a9-9c48-cddceb4087c6' User entered 'None (0)' | System           | 14 Oct 2020 00:17:12 |
|  | System           | 14 Oct 2020 00:17:12 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-13T20:17:04', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'd8bc3cc7-5317-40a9-9c48-cddceb4087c6' User entered 'None (0)' | System           | 14 Oct 2020 00:17:12 |
|  | System           | 14 Oct 2020 00:17:12 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-13T20:17:05', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'd8bc3cc7-5317-40a9-9c48-cddceb4087c6' User entered 'None (0)' | System           | 14 Oct 2020 00:17:12 |
|  | System           | 14 Oct 2020 00:17:12 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-13T20:17:09', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'd8bc3cc7-5317-40a9-9c48-cddceb4087c6' User entered 'No (N)' | System           | 14 Oct 2020 00:17:12 |
|  | System           | 14 Oct 2020 00:17:12 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-13T20:17:10', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'd8bc3cc7-5317-40a9-9c48-cddceb4087c6' User entered '13 Oct 2020 20:17' | System           | 14 Oct 2020 00:17:12 |
|   | System           | 14 Oct 2020 00:17:12 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:29

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '13 Oct 2020 12:00' | System           | 09 Oct 2020 17:23:55 |



**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '14 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 6' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T05:21:03', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '7d7e4033-44cc-442f-8ecb-06da86ba447a' | System           | 15 Oct 2020 09:21:16 |
| User entered 'No interference with activity (1)'   | System           | 15 Oct 2020 09:21:16 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T05:21:05', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '7d7e4033-44cc-442f-8ecb-06da86ba447a' | System           | 15 Oct 2020 09:21:16 |
| User entered 'No interference with activity (1)'   | System           | 15 Oct 2020 09:21:16 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T05:21:07', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '7d7e4033-44cc-442f-8ecb-06da86ba447a' | System           | 15 Oct 2020 09:21:16 |
| User entered 'No interference with activity (1)'   | System           | 15 Oct 2020 09:21:16 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T05:21:09', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '7d7e4033-44cc-442f-8ecb-06da86ba447a' User entered 'None (0)' | System           | 15 Oct 2020 09:21:16 |
|  | System           | 15 Oct 2020 09:21:16 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T05:21:10', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '7d7e4033-44cc-442f-8ecb-06da86ba447a' User entered 'None (0)' | System           | 15 Oct 2020 09:21:16 |
|  | System           | 15 Oct 2020 09:21:16 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T05:21:11', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '7d7e4033-44cc-442f-8ecb-06da86ba447a' User entered 'None (0)' | System           | 15 Oct 2020 09:21:16 |
|  | System           | 15 Oct 2020 09:21:16 |



US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T05:21:12', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '7d7e4033-44cc-442f-8ecb-06da86ba447a' User entered 'No (N)' | System           | 15 Oct 2020 09:21:16 |
|  | System           | 15 Oct 2020 09:21:16 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:29

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T05:21:14', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '7d7e4033-44cc-442f-8ecb-06da86ba447a' User entered '15 Oct 2020 05:21' | System           | 15 Oct 2020 09:21:16 |
|   | System           | 15 Oct 2020 09:21:16 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '14 Oct 2020 12:00' | System           | 09 Oct 2020 17:23:55 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '15 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 09 Oct 2020 17:23:55 |
| User entered 'Day 7' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T21:07:53', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2ce797f7-ff3f-4b87-adba-065a628a3204' User entered 'None (0)' | System           | 16 Oct 2020 01:08:13 |
|  | System           | 16 Oct 2020 01:08:13 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T21:07:56', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2ce797f7-ff3f-4b87-adba-065a628a3204' User entered 'None (0)' | System           | 16 Oct 2020 01:08:13 |
|  | System           | 16 Oct 2020 01:08:13 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T21:07:59', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2ce797f7-ff3f-4b87-adba-065a628a3204' User entered 'None (0)' | System           | 16 Oct 2020 01:08:13 |
|  | System           | 16 Oct 2020 01:08:13 |



US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T21:08:01', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2ce797f7-ff3f-4b87-adba-065a628a3204' User entered 'None (0)' | System           | 16 Oct 2020 01:08:13 |
|  | System           | 16 Oct 2020 01:08:13 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T21:08:02', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2ce797f7-ff3f-4b87-adba-065a628a3204' User entered 'None (0)' | System           | 16 Oct 2020 01:08:13 |
|  | System           | 16 Oct 2020 01:08:13 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T21:08:03', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2ce797f7-ff3f-4b87-adba-065a628a3204' User entered 'None (0)' | System           | 16 Oct 2020 01:08:13 |
|  | System           | 16 Oct 2020 01:08:13 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T21:08:05', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2ce797f7-ff3f-4b87-adba-065a628a3204' | System           | 16 Oct 2020 01:08:13 |
| User entered 'No (N)'  | System           | 16 Oct 2020 01:08:13 |

US3802168

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:29

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-15T21:08:07', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '2ce797f7-ff3f-4b87-adba-065a628a3204' User entered '15 Oct 2020 21:08' | System           | 16 Oct 2020 01:08:13 |
|   | System           | 16 Oct 2020 01:08:13 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '15 Oct 2020 12:00' | System           | 09 Oct 2020 17:23:55 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '16 Oct 2020 11:59' | System           | 09 Oct 2020 17:23:55 |

US3802168

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 15 Oct 2020 09:21:04 |
| User entered 'Day 8' | System           | 15 Oct 2020 09:21:04 |



US3802168

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:58:29

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-16T23:00:22', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'bb422561-b73d-4591-b558-6911a1eeb266' | System           | 17 Oct 2020 03:00:28 |
| User entered 'No (N)'  | System           | 17 Oct 2020 03:00:28 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-16T23:00:25', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'bb422561-b73d-4591-b558-6911a1eeb266' | System           | 17 Oct 2020 03:00:28 |
| User entered '16 Oct 2020 23:00'   | System           | 17 Oct 2020 03:00:28 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '16 Oct 2020 12:00' | System           | 15 Oct 2020 09:21:04 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '17 Oct 2020 11:59' | System           | 15 Oct 2020 09:21:04 |

US3802168

Folder: Diary Dose 2 (1)

Form: Underarm Gland\_Day(8)

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.   | System           | 15 Oct 2020 09:21:04 |
| User entered 'Day 8' | System           | 15 Oct 2020 09:21:04 |

US3802168

Folder: Diary Dose 2 (1)

Form: Underarm Gland\_Day(8)

Generated On: 10 Jun 2021 09:58:29

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-16T23:00:28', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b0b7270e-dece-4c30-a118-2fa855314f5a' User entered 'None (1)' | System           | 17 Oct 2020 03:00:36 |
|  | System           | 17 Oct 2020 03:00:36 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: Underarm Gland\_Day(8)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-10-16T23:00:30', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b0b7270e-dece-4c30-a118-2fa855314f5a' User entered '16 Oct 2020 23:00' | System           | 17 Oct 2020 03:00:36 |
|   | System           | 17 Oct 2020 03:00:36 |

**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: Underarm Gland\_Day(8)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Open Date and Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '16 Oct 2020 12:00' | System           | 15 Oct 2020 09:21:04 |



**US3802168**

**Folder: Diary Dose 2 (1)**

**Form: Underarm Gland\_Day(8)**

**Generated On: 10 Jun 2021 09:58:29**

[PC Close Date and Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| User entered '17 Oct 2020 11:59' | System           | 15 Oct 2020 09:21:04 |

**US3802168**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Was Contact Attempted?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jennifer Nagg (b) (4) | 19 Oct 2020 12:49:24 |

**US3802168**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:14 |
| User entered '18 Oct 2020' | (b) (4)<br>Jennifer Nagg (b) (4) | 19 Oct 2020 12:49:24 |

US3802168

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:29

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded.                  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:14 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Jennifer Nagg (b) (4) | 19 Oct 2020 12:49:24 |

US3802168

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:29

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:14 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 19 Oct 2020 12:49:24 |

US3802168

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:29

[Is the participant continuing to the next visit?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jennifer Nagg (b) (4) | 19 Oct 2020 12:49:29 |

**US3802168**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'I'  | System           | 19 Oct 2020 12:49:29 |

**US3802168**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Was Contact Attempted?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lalicia Roman (b) (4) | 30 Oct 2020 19:33:25 |



**US3802168**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:14 |
| User entered '23 Oct 2020' | (b) (4)<br>Lalicia Roman (b) (4) | 30 Oct 2020 19:33:25 |

US3802168

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:29

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded.                  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:14 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Lalicia Roman (b) (4) | 30 Oct 2020 19:33:25 |

**US3802168**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered empty.       | Lalicia Roman (b) (4)<br>(b) (4) | 30 Oct 2020 19:33:25 |

US3802168

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:29

[Is the participant continuing to the next visit?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lalicia Roman (b) (4) | 30 Oct 2020 19:33:13 |

**US3802168**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'I'  | System           | 30 Oct 2020 19:33:13 |

**US3802168**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Was Contact Attempted?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lalicia Roman (b) (4) | 30 Oct 2020 19:33:55 |

**US3802168**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:14 |
| User entered '30 Oct 2020' | (b) (4)<br>Lalicia Roman (b) (4) | 30 Oct 2020 19:33:55 |

**US3802168**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded.                  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:14 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Lalicia Roman (b) (4) | 30 Oct 2020 19:33:55 |



US3802168

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:29

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4) | 01 Feb 2021 16:26:14 |
| User entered empty.       | Lalicia Roman (b) (4) | 30 Oct 2020 19:33:55 |

US3802168

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:29

[Is the participant continuing to the next visit?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lalicia Roman (b) (4) | 30 Oct 2020 19:34:01 |

**US3802168**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'I'  | System           | 30 Oct 2020 19:34:01 |

**US3802168**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Was this visit performed?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Nov 2020 18:35:01 |

US3802168

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:29

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '9 Nov 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Nov 2020 18:35:01 |

**US3802168**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                                       | Time (GMT)           |
|--------------------------------|--|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded.      | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Nov 2020 18:35:01 |

**US3802168**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
| User entered 'VISIT3' | System           | 09 Nov 2020 18:35:01 |

US3802168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Were vital signs assessed?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Nov 2020 18:35:27 |



US3802168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '9 Nov 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Nov 2020 18:35:27 |

US3802168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Time of assessment (00:00-23:59)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '13:03'      | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Nov 2020 18:35:27 |

**US3802168**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
| User entered '9 Nov 2020 13:03' | System           | 09 Nov 2020 18:35:27 |

US3802168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Temperature (xxx.x)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '97.4' F     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Nov 2020 18:35:27 |

US3802168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Route of measurement](#)

| Audit                        | User                                       | Time (GMT)           |
|------------------------------|--|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded.    | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'Other (Other)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Nov 2020 18:35:27 |

**US3802168**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[If Other, specify](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'Infrared'   | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Nov 2020 18:35:27 |

US3802168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Pulse \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered '86'         | Emily Carney (b) (4)<br>(b) (4)  | 09 Nov 2020 18:35:27 |

**US3802168**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
| User entered 'bpm' | System           | 09 Nov 2020 18:35:27 |



US3802168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '18'         | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Nov 2020 18:35:27 |

US3802168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
| User entered 'breaths/min' | System           | 09 Nov 2020 18:35:27 |

US3802168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered '136'        | Emily Carney (b) (4)<br>(b) (4)  | 09 Nov 2020 18:35:27 |

**US3802168**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
| User entered 'mmHg' | System           | 09 Nov 2020 18:35:27 |

US3802168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Diastolic Blood Pressure (xxx)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '86'         | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Nov 2020 18:35:27 |

**US3802168**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
| User entered 'mmHg' | System           | 09 Nov 2020 18:35:27 |

**US3802168**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
|                   |                  |                      |

US3802168

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
|                   |                  |                      |



US3802168

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:29

[Was the physical examination performed?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Nov 2020 18:35:32 |

US3802168

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:29

Date of examination (*dd MMM yyyy*)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered empty.       | Emily Carney (b) (4)<br>(b) (4)  | 09 Nov 2020 18:35:32 |

US3802168

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:29

[Was the sample collected?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)           | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 09 Nov 2020 18:35:41 |

US3802168

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:29

Collection date (*dd MMM yyyy*)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '9 Nov 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Nov 2020 18:35:41 |

**US3802168**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:58:29**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered '13:13'      | Emily Carney (b) (4)<br>(b) (4)  | 09 Nov 2020 18:35:41 |

**US3802168**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:58:29**

[Collection date and time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
| User entered '9 Nov 2020 13:13' | System           | 09 Nov 2020 18:35:41 |

US3802168

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:29

[Is the participant continuing to the next visit?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 12:19:09 |
| User signature succeeded. | Judith Martin (b) (4)           | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 09 Nov 2020 18:36:25 |

**US3802168**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 12:19:09 |
| User entered 'I'  | System           | 09 Nov 2020 18:36:25 |



US3802168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.    | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 64' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

[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)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-11-08T04:46:13', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '72782b4e-4dd9-498d-9d69-4ccf32989c14' User entered 'No (N)' | System           | 08 Nov 2020 09:46:19 |
|  | System           | 08 Nov 2020 09:46:19 |

US3802168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

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)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-11-08T04:45:56', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '72782b4e-4dd9-498d-9d69-4ccf32989c14' User entered 'No (N)' | System           | 08 Nov 2020 09:46:19 |
|  | System           | 08 Nov 2020 09:46:19 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-11-08T04:46:17', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '72782b4e-4dd9-498d-9d69-4ccf32989c14' User entered '08 Nov 2020 04:46:17' | System           | 08 Nov 2020 09:46:19 |
|  | System           | 08 Nov 2020 09:46:19 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.               | System           | 08 Sep 2020 15:16:51 |
| User entered '08 Nov 2020 00:01' | System           | 08 Sep 2020 15:16:51 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.               | System           | 08 Sep 2020 15:16:51 |
| User entered '12 Nov 2020 23:59' | System           | 08 Sep 2020 15:16:51 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.    | System           | 08 Sep 2020 15:16:51 |
| User entered 'Day 71' | System           | 08 Sep 2020 15:16:51 |

US3802168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

[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)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-11-16T19:50:16', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c9438cca-2904-47c1-b755-f89c59cc98e1' User entered 'No (N)' | System           | 17 Nov 2020 00:50:24 |
|  | System           | 17 Nov 2020 00:50:24 |



US3802168

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:29

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)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-11-16T19:50:18', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c9438cca-2904-47c1-b755-f89c59cc98e1' User entered 'No (N)' | System           | 17 Nov 2020 00:50:24 |
|  | System           | 17 Nov 2020 00:50:24 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-11-16T19:50:20', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'c9438cca-2904-47c1-b755-f89c59cc98e1' User entered '16 Nov 2020 19:50:20' | System           | 17 Nov 2020 00:50:24 |
|  | System           | 17 Nov 2020 00:50:24 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.               | System           | 08 Sep 2020 15:16:51 |
| User entered '15 Nov 2020 00:01' | System           | 08 Sep 2020 15:16:51 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 06 Mar 2021 23:22:52 |
| Data entry locked.               | System           | 08 Sep 2020 15:16:51 |
| User entered '19 Nov 2020 23:59' | System           | 08 Sep 2020 15:16:51 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 75' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '19 Nov 2020 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '23 Nov 2020 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 82' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-11-26T05:10:18', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '5a5f82e9-897a-46fe-be1c-ccea4c74a9e7' User entered 'No (N)' | System | 26 Nov 2020 10:10:32 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-11-26T05:10:22', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '5a5f82e9-897a-46fe-be1c-ccea4c74a9e7' User entered 'No (N)' | System | 26 Nov 2020 10:10:32 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-11-26T05:10:29', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '5a5f82e9-897a-46fe-be1c-ccea4c74a9e7' User entered '26 Nov 2020 05:10:29' | System | 26 Nov 2020 10:10:32 |
|  | System | 26 Nov 2020 10:10:32 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '26 Nov 2020 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '30 Nov 2020 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-12-05T12:00:29', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '44fff20d-14f9-408b-9a3d-f6f989fc3055' | System | 05 Dec 2020 17:00:39 |
| User entered 'No (N)'  | System | 05 Dec 2020 17:00:39 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-12-05T12:00:31', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '44fff20d-14f9-408b-9a3d-f6f989fc3055' | System | 05 Dec 2020 17:00:39 |
| User entered 'No (N)'  | System | 05 Dec 2020 17:00:39 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-12-05T12:00:33', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '44fff20d-14f9-408b-9a3d-f6f989fc3055' | System | 05 Dec 2020 17:00:39 |
| User entered '05 Dec 2020 12:00:33'  | System | 05 Dec 2020 17:00:39 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '03 Dec 2020 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '07 Dec 2020 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-12-12T10:20:07', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b81c6af4-b37e-4877-9dff-2536787088b3' User entered 'No (N)' | System | 12 Dec 2020 15:20:15 |
|  | System | 12 Dec 2020 15:20:15 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-12-12T10:20:08', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b81c6af4-b37e-4877-9dff-2536787088b3' User entered 'No (N)' | System | 12 Dec 2020 15:20:15 |
|  | System | 12 Dec 2020 15:20:15 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-12-12T10:20:12', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'b81c6af4-b37e-4877-9dff-2536787088b3' | System | 12 Dec 2020 15:20:15 |
| User entered '12 Dec 2020 10:20:12'  | System | 12 Dec 2020 15:20:15 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '10 Dec 2020 00:01' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '14 Dec 2020 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-12-17T05:42:32', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'ebef2cad-5c06-415c-a07c-a9ab499c8cbf' User entered 'No (N)' | System | 17 Dec 2020 10:42:40 |
|  | System | 17 Dec 2020 10:42:40 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-12-17T05:42:34', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'ebef2cad-5c06-415c-a07c-a9ab499c8cbf' User entered 'No (N)' | System | 17 Dec 2020 10:42:40 |
|  | System | 17 Dec 2020 10:42:40 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-12-17T05:42:37', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'ebef2cad-5c06-415c-a07c-a9ab499c8cbf' User entered '17 Dec 2020 05:42:37' | System | 17 Dec 2020 10:42:40 |
|  | System | 17 Dec 2020 10:42:40 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '17 Dec 2020 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '21 Dec 2020 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-12-24T20:50:07', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'bcd31e5-6d7a-4563-8904-b7faaa52d5db' User entered 'No (N)' | System | 25 Dec 2020 01:50:16 |
|   | System | 25 Dec 2020 01:50:16 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-12-24T20:50:09', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'bcd31e5-6d7a-4563-8904-b7faaa52d5db' User entered 'No (N)' | System | 25 Dec 2020 01:50:16 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-12-24T20:50:15', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'bcd31e5-6d7a-4563-8904-b7faaa52d5db' User entered '24 Dec 2020 20:50:15' | System | 25 Dec 2020 01:50:16 |
|   | System | 25 Dec 2020 01:50:16 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '24 Dec 2020 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '28 Dec 2020 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-12-31T05:57:24', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e48b49e8-9952-47fe-9c67-fdd70fa18b3a' User entered 'No (N)' | System | 31 Dec 2020 10:57:33 |
|  | System | 31 Dec 2020 10:57:33 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-12-31T05:57:26', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e48b49e8-9952-47fe-9c67-fdd70fa18b3a' User entered 'No (N)' | System | 31 Dec 2020 10:57:33 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2020-12-31T05:57:29', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e48b49e8-9952-47fe-9c67-fdd70fa18b3a' User entered '31 Dec 2020 05:57:29' | System | 31 Dec 2020 10:57:33 |
|  | System | 31 Dec 2020 10:57:33 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '31 Dec 2020 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '04 Jan 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-01-09T12:21:40', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '3e34119c-f014-4045-a40d-2c704663da33' User entered 'No (N)' | System | 09 Jan 2021 17:21:48 |
|  | System | 09 Jan 2021 17:21:48 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-01-09T12:21:43', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '3e34119c-f014-4045-a40d-2c704663da33' User entered 'No (N)' | System | 09 Jan 2021 17:21:48 |
|  | System | 09 Jan 2021 17:21:48 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-01-09T12:21:45', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '3e34119c-f014-4045-a40d-2c704663da33' User entered '09 Jan 2021 12:21:45' | System | 09 Jan 2021 17:21:48 |
|  | System | 09 Jan 2021 17:21:48 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '07 Jan 2021 00:01' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '11 Jan 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-01-14T06:10:40', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '97a2c42d-c880-476a-942e-34fe441c914c' User entered 'No (N)' | System | 14 Jan 2021 11:10:48 |
|  | System | 14 Jan 2021 11:10:48 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-01-14T06:10:42', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '97a2c42d-c880-476a-942e-34fe441c914c' User entered 'No (N)' | System | 14 Jan 2021 11:10:48 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-01-14T06:10:44', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '97a2c42d-c880-476a-942e-34fe441c914c' User entered '14 Jan 2021 06:10:44' | System | 14 Jan 2021 11:10:48 |
|  | System | 14 Jan 2021 11:10:48 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '14 Jan 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '18 Jan 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-01-21T05:48:22', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '8455ec06-460d-4746-8eec-f48b760c1f87' | System | 21 Jan 2021 10:48:27 |
| User entered 'No (N)'  | System | 21 Jan 2021 10:48:27 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-01-21T05:48:24', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '8455ec06-460d-4746-8eec-f48b760c1f87' | System | 21 Jan 2021 10:48:27 |
| User entered 'No (N)'  | System | 21 Jan 2021 10:48:27 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-01-21T05:48:26', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '8455ec06-460d-4746-8eec-f48b760c1f87' User entered '21 Jan 2021 05:48:26' | System | 21 Jan 2021 10:48:27 |
|  | System | 21 Jan 2021 10:48:27 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '21 Jan 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '25 Jan 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 145' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-01-31T05:55:03', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a9388378-36bd-434a-9812-08c72b214655' | System | 31 Jan 2021 10:55:09 |
| User entered 'No (N)'  | System | 31 Jan 2021 10:55:09 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-01-31T05:55:04', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a9388378-36bd-434a-9812-08c72b214655' | System | 31 Jan 2021 10:55:09 |
| User entered 'No (N)'  | System | 31 Jan 2021 10:55:09 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-01-31T05:55:07', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'a9388378-36bd-434a-9812-08c72b214655' User entered '31 Jan 2021 05:55:07' | System | 31 Jan 2021 10:55:09 |
|  | System | 31 Jan 2021 10:55:09 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '28 Jan 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '01 Feb 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 152' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-02-04T06:13:38', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '91d6f2e2-4c32-435e-95c8-a19dcbe319e1' User entered 'No (N)' | System | 04 Feb 2021 11:13:43 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-02-04T06:13:39', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '91d6f2e2-4c32-435e-95c8-a19dcbe319e1' User entered 'No (N)' | System | 04 Feb 2021 11:13:43 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-02-04T06:13:41', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '91d6f2e2-4c32-435e-95c8-a19dcbe319e1' User entered '04 Feb 2021 06:13:41' | System | 04 Feb 2021 11:13:43 |
|  | System | 04 Feb 2021 11:13:43 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '04 Feb 2021 00:01' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '08 Feb 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 159' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-02-12T05:33:05', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '6b2b5340-fdef-422e-ba5c-bb94462cdc35' | System | 12 Feb 2021 10:33:16 |
| User entered 'No (N)'  | System | 12 Feb 2021 10:33:16 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-02-12T05:33:08', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '6b2b5340-fdef-422e-ba5c-bb94462cdc35' | System | 12 Feb 2021 10:33:16 |
| User entered 'No (N)'  | System | 12 Feb 2021 10:33:16 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-02-12T05:33:10', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '6b2b5340-fdef-422e-ba5c-bb94462cdc35' | System | 12 Feb 2021 10:33:16 |
| User entered '12 Feb 2021 05:33:10'  | System | 12 Feb 2021 10:33:16 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '11 Feb 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '15 Feb 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 166' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-02-18T19:07:31', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '94dff5df-0d16-46e0-8333-927e1ca33057' | System | 19 Feb 2021 00:12:38 |
| User entered 'No (N)'  | System | 19 Feb 2021 00:12:38 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-02-18T19:07:32', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '94dff5df-0d16-46e0-8333-927e1ca33057' | System | 19 Feb 2021 00:12:38 |
| User entered 'No (N)'  | System | 19 Feb 2021 00:12:38 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-02-18T19:07:35', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '94dff5df-0d16-46e0-8333-927e1ca33057' | System | 19 Feb 2021 00:12:38 |
| User entered '18 Feb 2021 19:07:35'  | System | 19 Feb 2021 00:12:38 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '18 Feb 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '22 Feb 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 173' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-02-27T15:59:27-05:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '0e229fdb-eb76-4944-b717-ac839052b39c' User entered 'No (N)' | System | 27 Feb 2021 20:59:34 |
|  | System | 27 Feb 2021 20:59:34 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-02-27T15:59:28-05:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '0e229fdb-eb76-4944-b717-ac839052b39c' | System | 27 Feb 2021 20:59:34 |
| User entered 'No (N)'  | System | 27 Feb 2021 20:59:34 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-02-27T15:59:30-05:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '0e229fdb-eb76-4944-b717-ac839052b39c' User entered '27 Feb 2021 20:59:30' | System | 27 Feb 2021 20:59:34 |
|  | System | 27 Feb 2021 20:59:34 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '25 Feb 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '01 Mar 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 180' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-03-07T17:59:23-05:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '170899fe-eede-41d1-a4a9-d20333206279' | System | 07 Mar 2021 22:59:36 |
| User entered 'No (N)'  | System | 07 Mar 2021 22:59:36 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-03-07T17:59:25-05:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '170899fe-eede-41d1-a4a9-d20333206279' | System | 07 Mar 2021 22:59:36 |
| User entered 'No (N)'  | System | 07 Mar 2021 22:59:36 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-03-07T17:59:28-05:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '170899fe-eede-41d1-a4a9-d20333206279' User entered '07 Mar 2021 17:59:28' | System | 07 Mar 2021 22:59:36 |
|  | System | 07 Mar 2021 22:59:36 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '04 Mar 2021 00:01' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '08 Mar 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 187' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-03-11T06:07:24-05:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'f927be50-4e3b-4c3f-832c-5ffe9c1c0690' | System | 11 Mar 2021 11:07:30 |
| User entered 'No (N)'  | System | 11 Mar 2021 11:07:30 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-03-11T06:07:25-05:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'f927be50-4e3b-4c3f-832c-5ffe9c1c0690' | System | 11 Mar 2021 11:07:30 |
| User entered 'No (N)'  | System | 11 Mar 2021 11:07:30 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-03-11T06:07:28-05:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'f927be50-4e3b-4c3f-832c-5ffe9c1c0690' User entered '11 Mar 2021 06:07:28' | System | 11 Mar 2021 11:07:30 |
|  | System | 11 Mar 2021 11:07:30 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '11 Mar 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '15 Mar 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 194' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-03-18T06:30:38-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '65752dff-1b91-4d42-9a31-37b31c4780ef' | System | 18 Mar 2021 10:30:45 |
| User entered 'No (N)'  | System | 18 Mar 2021 10:30:45 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-03-18T06:30:40-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '65752dff-1b91-4d42-9a31-37b31c4780ef' | System | 18 Mar 2021 10:30:45 |
| User entered 'No (N)'  | System | 18 Mar 2021 10:30:45 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-03-18T06:30:43-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '65752dff-1b91-4d42-9a31-37b31c4780ef' User entered '18 Mar 2021 06:30:43' | System | 18 Mar 2021 10:30:45 |
|  | System | 18 Mar 2021 10:30:45 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '18 Mar 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '22 Mar 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 201' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-03-27T12:09:00-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '98619ff6-21f9-4b02-b56a-e609146ed2be' | System | 27 Mar 2021 16:13:27 |
| User entered 'No (N)'  | System | 27 Mar 2021 16:13:27 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-03-27T12:09:02-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '98619ff6-21f9-4b02-b56a-e609146ed2be' | System | 27 Mar 2021 16:13:27 |
| User entered 'No (N)'  | System | 27 Mar 2021 16:13:27 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-03-27T12:09:05-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '98619ff6-21f9-4b02-b56a-e609146ed2be' | System | 27 Mar 2021 16:13:27 |
| User entered '27 Mar 2021 12:09:05'  | System | 27 Mar 2021 16:13:27 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '25 Mar 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '29 Mar 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 208' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-01T01:58:18-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e8cad018-d9cb-4562-8488-6dfca5261a91' | System | 01 Apr 2021 05:58:47 |
| User entered 'Yes (Y)'   | System | 01 Apr 2021 05:58:47 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-01T01:58:20-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e8cad018-d9cb-4562-8488-6dfca5261a91' | System | 01 Apr 2021 05:58:47 |
| User entered 'No (N)'  | System | 01 Apr 2021 05:58:47 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-01T01:58:22-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e8cad018-d9cb-4562-8488-6dfca5261a91' | System | 01 Apr 2021 05:58:47 |
| User entered 'No (N)'  | System | 01 Apr 2021 05:58:47 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-01T01:58:40-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e8cad018-d9cb-4562-8488-6dfca5261a91' | System | 01 Apr 2021 05:58:47 |
| User entered 'No (N)'  | System | 01 Apr 2021 05:58:47 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-01T01:58:44-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e8cad018-d9cb-4562-8488-6dfca5261a91' | System | 01 Apr 2021 05:58:47 |
| User entered '01 Apr 2021 01:58:44'  | System | 01 Apr 2021 05:58:47 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '01 Apr 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '05 Apr 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 215' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-09T12:33:28-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '355697e8-3101-4e23-ad5a-6987c4a5de59' | System | 09 Apr 2021 16:33:57 |
| User entered 'Yes (Y)'   | System | 09 Apr 2021 16:33:57 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-09T12:33:33-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '355697e8-3101-4e23-ad5a-6987c4a5de59' | System | 09 Apr 2021 16:33:57 |
| User entered 'No (N)'  | System | 09 Apr 2021 16:33:57 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-09T12:33:35-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '355697e8-3101-4e23-ad5a-6987c4a5de59' | System | 09 Apr 2021 16:33:57 |
| User entered 'No (N)'  | System | 09 Apr 2021 16:33:57 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-09T12:33:38-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '355697e8-3101-4e23-ad5a-6987c4a5de59' | System | 09 Apr 2021 16:33:57 |
| User entered 'Yes (Y)'   | System | 09 Apr 2021 16:33:57 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-09T12:33:43-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '355697e8-3101-4e23-ad5a-6987c4a5de59' | System | 09 Apr 2021 16:33:57 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 09 Apr 2021 16:33:57 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-09T12:33:46-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '355697e8-3101-4e23-ad5a-6987c4a5de59' | System | 09 Apr 2021 16:33:57 |
| User entered '09 Apr 2021 12:33:46'  | System | 09 Apr 2021 16:33:57 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '08 Apr 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '12 Apr 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 222' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-15T01:33:36-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '97047890-33ea-4e77-9344-861ab0ffe239' | System | 15 Apr 2021 05:34:01 |
| User entered 'Yes (Y)'   | System | 15 Apr 2021 05:34:01 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-15T01:33:39-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '97047890-33ea-4e77-9344-861ab0ffe239' | System | 15 Apr 2021 05:34:01 |
| User entered 'No (N)'  | System | 15 Apr 2021 05:34:01 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-15T01:33:42-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '97047890-33ea-4e77-9344-861ab0ffe239' | System | 15 Apr 2021 05:34:01 |
| User entered 'No (N)'  | System | 15 Apr 2021 05:34:01 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-15T01:33:45-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '97047890-33ea-4e77-9344-861ab0ffe239' | System | 15 Apr 2021 05:34:01 |
| User entered 'Yes (Y)'   | System | 15 Apr 2021 05:34:01 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-15T01:33:46-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '97047890-33ea-4e77-9344-861ab0ffe239' | System | 15 Apr 2021 05:34:01 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 15 Apr 2021 05:34:01 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-15T01:33:50-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '97047890-33ea-4e77-9344-861ab0ffe239' | System | 15 Apr 2021 05:34:01 |
| User entered '15 Apr 2021 01:33:50'  | System | 15 Apr 2021 05:34:01 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '15 Apr 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '19 Apr 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 229' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-22T02:24:28-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '97cecb1f-bdf0-4551-ae24-3721d9cf434f' User entered 'No (N)' | System | 22 Apr 2021 06:24:36 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-22T02:24:29-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '97cecb1f-bdf0-4551-ae24-3721d9cf434f' User entered 'No (N)' | System | 22 Apr 2021 06:24:36 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-04-22T02:24:32-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: '97cecb1f-bdf0-4551-ae24-3721d9cf434f' | System | 22 Apr 2021 06:24:36 |
| User entered '22 Apr 2021 02:24:32'  | System | 22 Apr 2021 06:24:36 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '22 Apr 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '26 Apr 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 236' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-05-01T12:00:11-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'd2f7a463-3e3e-4cc8-adb4-b6194d8d617f' | System | 01 May 2021 16:00:19 |
| User entered 'No (N)'  | System | 01 May 2021 16:00:19 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[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 (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-05-01T12:00:12-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'd2f7a463-3e3e-4cc8-adb4-b6194d8d617f' | System | 01 May 2021 16:00:19 |
| User entered 'No (N)'  | System | 01 May 2021 16:00:19 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-05-01T12:00:15-04:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'd2f7a463-3e3e-4cc8-adb4-b6194d8d617f' | System | 01 May 2021 16:00:19 |
| User entered '01 May 2021 12:00:15'  | System | 01 May 2021 16:00:19 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '29 Apr 2021 00:01' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '03 May 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 243' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '06 May 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '10 May 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 250' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '13 May 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '17 May 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 257' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '20 May 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '24 May 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 264' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '27 May 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '31 May 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 271' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '03 Jun 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '07 Jun 2021 23:59' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 278' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '10 Jun 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '14 Jun 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 285' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '17 Jun 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '21 Jun 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 292' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '24 Jun 2021 00:01' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '28 Jun 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 299' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '01 Jul 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '05 Jul 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 306' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '08 Jul 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '12 Jul 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 313' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '15 Jul 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '19 Jul 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 320' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '22 Jul 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '26 Jul 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 327' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '29 Jul 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '02 Aug 2021 23:59' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 334' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '05 Aug 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '09 Aug 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 341' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '12 Aug 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '16 Aug 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 348' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '19 Aug 2021 00:01' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '23 Aug 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 355' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '26 Aug 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '30 Aug 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 362' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '02 Sep 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '06 Sep 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 369' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '09 Sep 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '13 Sep 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 376' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '16 Sep 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '20 Sep 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 383' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '23 Sep 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '27 Sep 2021 23:59' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 390' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '30 Sep 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '04 Oct 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 397' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '07 Oct 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '11 Oct 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 404' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '14 Oct 2021 00:01' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '18 Oct 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 411' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '21 Oct 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '25 Oct 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 418' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '28 Oct 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '01 Nov 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 425' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '04 Nov 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '08 Nov 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 432' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '11 Nov 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '15 Nov 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 439' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '18 Nov 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '22 Nov 2021 23:59' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 446' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '25 Nov 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '29 Nov 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 453' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '02 Dec 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '06 Dec 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 460' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '09 Dec 2021 00:01' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '13 Dec 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 467' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '16 Dec 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '20 Dec 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 474' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '23 Dec 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '27 Dec 2021 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 481' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '30 Dec 2021 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '03 Jan 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 488' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '06 Jan 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '10 Jan 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 495' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '13 Jan 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '17 Jan 2022 23:59' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 502' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '20 Jan 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '24 Jan 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 509' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '27 Jan 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '31 Jan 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 516' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '03 Feb 2022 00:01' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '07 Feb 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 523' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '10 Feb 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '14 Feb 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 530' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '17 Feb 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '21 Feb 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 537' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '24 Feb 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '28 Feb 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 544' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '03 Mar 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '07 Mar 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 551' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '10 Mar 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '14 Mar 2022 23:59' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 558' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '17 Mar 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '21 Mar 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 565' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '24 Mar 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '28 Mar 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 572' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '31 Mar 2022 00:01' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '04 Apr 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 579' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '07 Apr 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '11 Apr 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 586' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '14 Apr 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '18 Apr 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 593' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '21 Apr 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '25 Apr 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 600' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '28 Apr 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '02 May 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 607' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '05 May 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '09 May 2022 23:59' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 614' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '12 May 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '16 May 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 621' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '19 May 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '23 May 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 628' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '26 May 2022 00:01' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '30 May 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 635' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '02 Jun 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '06 Jun 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 642' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '09 Jun 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '13 Jun 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 649' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '16 Jun 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '20 Jun 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 656' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '23 Jun 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '27 Jun 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 663' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '30 Jun 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '04 Jul 2022 23:59' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 670' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '07 Jul 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '11 Jul 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 677' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '14 Jul 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '18 Jul 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 684' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '21 Jul 2022 00:01' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '25 Jul 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 691' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '28 Jul 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '01 Aug 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 698' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '04 Aug 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '08 Aug 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 705' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '11 Aug 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '15 Aug 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 712' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '18 Aug 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '22 Aug 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 719' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '25 Aug 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '29 Aug 2022 23:59' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

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**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 726' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '01 Sep 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '05 Sep 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

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**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 733' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '08 Sep 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

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**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '12 Sep 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

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**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 740' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '15 Sep 2022 00:01' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

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**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '19 Sep 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

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**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 747' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '22 Sep 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '26 Sep 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

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**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 754' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '29 Sep 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '03 Oct 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 761' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '06 Oct 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '10 Oct 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 768' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '13 Oct 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '17 Oct 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 775' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '20 Oct 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '24 Oct 2022 23:59' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 782' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '27 Oct 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '31 Oct 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 789' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '03 Nov 2022 00:01' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '07 Nov 2022 23:59' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered 'Day 796' | System | 20 Nov 2020 06:02:25 |

**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '10 Nov 2022 00:01' | System | 20 Nov 2020 06:02:25 |



**US3802168**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:29**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 06:02:25 |
| Amendment Manager: User entered '14 Nov 2022 23:59' | System | 20 Nov 2020 06:02:25 |

US3802168

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:58:29

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 17:03:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-02-27T15:59:21-05:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e085b1d6-15e1-4559-bf95-41a11a6366d8' User entered 'No (N)' | System           | 27 Feb 2021 20:59:26 |
|  | System           | 27 Feb 2021 20:59:26 |

**US3802168**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Date & Time of Submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 17:03:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D2C8053B-41A3-4101-ACB5-72B73C498F66)', Time: '2021-02-27T15:59:24-05:00', User OID: 'PatientReportedOutcome (US3802168)', ODM File OID: 'e085b1d6-15e1-4559-bf95-41a11a6366d8' User entered '27 Feb 2021 20:59:24' | System           | 27 Feb 2021 20:59:26 |
|  | System           | 27 Feb 2021 20:59:26 |

**US3802168**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Was Contact Attempted?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 04 Dec 2020 19:54:36 |

**US3802168**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

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

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '4 Dec 2020' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 04 Dec 2020 19:54:36 |

**US3802168**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded.                  | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered 'Contact Made (CONTACT MADE)' | Emily Carney (b) (4)<br>(b) (4)  | 04 Dec 2020 19:54:36 |

**US3802168**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 04 Dec 2020 19:54:36 |

US3802168

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:29

[Is the participant continuing to the next visit?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Mar 2021 12:17:58 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)<br>(b) (4)  | 04 Dec 2020 19:54:30 |



**US3802168**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 12:17:58 |
| User entered 'I'  | System           | 04 Dec 2020 19:54:30 |

**US3802168**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Was Contact Attempted?](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 14 Apr 2021 11:08:23 |
| User signature succeeded. | Judith Martin (b) (4)          | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Matthew Lee (b) (4) | 08 Jan 2021 20:41:46 |

**US3802168**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 14 Apr 2021 11:08:23 |
| User signature succeeded.                                     | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User entered '5 Jan 2021' reason for change: Data Entry Error | (b) (4)               |                      |
|   | Matthew Lee (b) (4)   | 08 Jan 2021 20:41:58 |
| User entered '8 Jan 2021'                                     | (b) (4)               |                      |
|   | Matthew Lee (b) (4)   | 08 Jan 2021 20:41:46 |
|   | (b) (4)               |                      |

**US3802168**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 14 Apr 2021 11:08:23 |
| User signature succeeded.                  | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User entered 'Contact Made (CONTACT MADE)' | Matthew Lee (b) (4)   | 08 Jan 2021 20:41:46 |

**US3802168**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 14 Apr 2021 11:08:23 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Matthew Lee (b) (4)<br>(b) (4) | 08 Jan 2021 20:41:46 |

US3802168

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:29

[Is the participant continuing to the next visit?](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 14 Apr 2021 11:08:23 |
| User signature succeeded. | Judith Martin (b) (4)          | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Matthew Lee (b) (4) | 08 Jan 2021 20:41:50 |

**US3802168**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:08:23 |
| User entered 'I'  | System           | 08 Jan 2021 20:41:50 |

**US3802168**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 11:08:23 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 12 Feb 2021 20:06:44 |



**US3802168**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 11:08:23 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered '9 Feb 2021' | Emily Carney (b) (4)  | 12 Feb 2021 20:06:44 |

**US3802168**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 14 Apr 2021 11:08:23 |
| User signature succeeded.                  | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered 'Contact Made (CONTACT MADE)' | Emily Carney (b) (4)  | 12 Feb 2021 20:06:44 |

**US3802168**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 11:08:23 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered empty.       | Emily Carney (b) (4)  | 12 Feb 2021 20:06:44 |

US3802168

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:29

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 11:08:23 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 12 Feb 2021 20:06:53 |

**US3802168**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:08:23 |
| User entered 'I'  | System           | 12 Feb 2021 20:06:53 |

**US3802168**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 11:08:23 |
| User signature succeeded. | Judith Martin (b) (4) | 05 Mar 2021 20:22:04 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 05 Mar 2021 15:37:29 |

**US3802168**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 11:08:23 |
| User signature succeeded. | Judith Martin (b) (4) | 05 Mar 2021 20:22:04 |
| User entered '5 Mar 2021' | Emily Carney (b) (4)  | 05 Mar 2021 15:37:29 |

**US3802168**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                | 14 Apr 2021 11:08:23 |
| User signature succeeded.                  | Judith Martin (b) (4)           | 05 Mar 2021 20:22:04 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Emily Carney (b) (4) | 05 Mar 2021 15:37:29 |



**US3802168**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 11:08:23 |
| User signature succeeded. | Judith Martin (b) (4) | 05 Mar 2021 20:22:04 |
| User entered empty.       | Emily Carney (b) (4)  | 05 Mar 2021 15:37:29 |

US3802168

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:29

[Is the participant continuing to the next visit?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 14 Apr 2021 11:08:23 |
| User signature succeeded. | Judith Martin (b) (4)           | 05 Mar 2021 20:22:04 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 05 Mar 2021 15:37:22 |

**US3802168**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:08:23 |
| User entered 'I'  | System           | 05 Mar 2021 15:37:22 |

**US3802168**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Was this visit performed?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 11:52:15 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:40:53 |
| User entered 'Yes (Y)'    | (b) (4)<br>Melissa Andrasko (b) (4) | 08 Apr 2021 18:01:13 |

US3802168

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:29

Visit date (dd MMM yyyy)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 11:52:15 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:40:53 |
| User entered '8 Apr 2021' | (b) (4)<br>Melissa Andrasko (b) (4) | 08 Apr 2021 18:01:13 |

**US3802168**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User   | Time (GMT)           |
|--------------------------------|--|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                               | 02 May 2021 11:52:15 |
| User signature succeeded.      | Judith Martin (b) (4)                          | 08 Apr 2021 18:40:53 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 08 Apr 2021 18:01:13 |

**US3802168**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 02 May 2021 11:52:15 |
| User entered 'VISIT4' | System           | 08 Apr 2021 18:01:13 |

US3802168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Were vital signs assessed?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 11:52:15 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:40:53 |
| User entered 'No (N)'     | (b) (4)<br>Melissa Andrasko (b) (4) | 08 Apr 2021 18:01:27 |



**US3802168**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

**Date of assessment** (*dd MMM yyyy*)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 11:52:15 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:40:53 |
| User entered empty.       | (b) (4)<br>Melissa Andrasko (b) (4) | 08 Apr 2021 18:01:27 |

**US3802168**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

**Time of assessment (00:00-23:59)**

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 02 May 2021 11:52:15 |
| User signature succeeded. | Judith Martin (b) (4)                          | 08 Apr 2021 18:40:53 |
| User entered empty.       | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 08 Apr 2021 18:01:27 |

**US3802168**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Vital Signs Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 11:52:15 |
| User entered empty. | System           | 08 Apr 2021 18:01:27 |

US3802168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Temperature (xxx.x)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 11:52:15 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:40:53 |
| User entered empty.       | (b) (4)<br>Melissa Andrasko (b) (4) | 08 Apr 2021 18:01:27 |

**US3802168**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Route of measurement](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 11:52:15 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:40:53 |
| User entered empty.       | (b) (4)<br>Melissa Andrasko (b) (4) | 08 Apr 2021 18:01:27 |

**US3802168**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[If Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 11:52:15 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:40:53 |
| User entered empty.       | (b) (4)<br>Melissa Andrasko (b) (4) | 08 Apr 2021 18:01:27 |

**US3802168**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Pulse \(xxx\)](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 11:52:15 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:40:53 |
| User entered empty.       | (b) (4)<br>Melissa Andrasko (b) (4) | 08 Apr 2021 18:01:27 |

**US3802168**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 11:52:15 |
| User entered empty. | System           | 08 Apr 2021 18:01:27 |



US3802168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 11:52:15 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:40:53 |
| User entered empty.       | (b) (4)<br>Melissa Andrasko (b) (4) | 08 Apr 2021 18:01:27 |

US3802168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 11:52:15 |
| User entered empty. | System           | 08 Apr 2021 18:01:27 |

US3802168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Systolic Blood Pressure (xxx)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 11:52:15 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:40:53 |
| User entered empty.       | (b) (4)<br>Melissa Andrasko (b) (4) | 08 Apr 2021 18:01:27 |

**US3802168**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 11:52:15 |
| User entered empty. | System           | 08 Apr 2021 18:01:27 |

US3802168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Diastolic Blood Pressure (xxx)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 02 May 2021 11:52:15 |
| User signature succeeded. | Judith Martin (b) (4)                          | 08 Apr 2021 18:40:53 |
| User entered empty.       | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 08 Apr 2021 18:01:27 |

**US3802168**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 11:52:15 |
| User entered empty. | System           | 08 Apr 2021 18:01:27 |

US3802168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:52:15 |
|                   |                  |                      |

US3802168

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:52:15 |
|                   |                  |                      |



US3802168

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:29

[Was the physical examination performed?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 11:52:15 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:40:53 |
| User entered 'No (N)'     | (b) (4)<br>Melissa Andrasko (b) (4) | 08 Apr 2021 18:01:34 |

**US3802168**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:58:29**

**Date of examination (dd MMM yyyy)**

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 02 May 2021 11:52:15 |
| User signature succeeded. | Judith Martin (b) (4)                          | 08 Apr 2021 18:40:53 |
| User entered empty.       | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 08 Apr 2021 18:01:34 |

**US3802168**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:58:29**

[Was the sample collected?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 02 May 2021 11:52:15 |
| User signature succeeded. | Judith Martin (b) (4)                          | 08 Apr 2021 18:40:53 |
| User entered 'Yes (Y)'    | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 08 Apr 2021 18:03:02 |

US3802168

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:29

Collection date (dd MMM yyyy)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 11:52:15 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:40:53 |
| User entered '8 Apr 2021' | (b) (4)<br>Melissa Andrasko (b) (4) | 08 Apr 2021 18:03:02 |

**US3802168**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:58:29**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 02 May 2021 11:52:15 |
| User signature succeeded. | Judith Martin (b) (4)               | 08 Apr 2021 18:40:53 |
| User entered '13:20'      | (b) (4)<br>Melissa Andrasko (b) (4) | 08 Apr 2021 18:03:02 |

**US3802168**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:58:29**

[Collection date and time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 02 May 2021 11:52:15 |
| User entered '8 Apr 2021 13:20' | System           | 08 Apr 2021 18:03:02 |

**US3802168**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Is the participant continuing to the next visit?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 02 May 2021 11:52:15 |
| User signature succeeded. | Judith Martin (b) (4)                          | 08 Apr 2021 18:40:53 |
| User entered 'Yes (Y)'    | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 08 Apr 2021 18:03:07 |

**US3802168**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:52:15 |
| User entered 'I'  | System           | 08 Apr 2021 18:03:07 |



**US3802168**

**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:58:29**

[Date of Contact](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)            | 23 Apr 2021 18:04:32 |
| User entered '19 Apr 2021' | (b) (4)<br>Lalicia Roman (b) (4) | 23 Apr 2021 17:07:16 |

US3802168

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:29

[Time of Contact](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 23 Apr 2021 18:04:32 |
|                           | (b) (4)               |                      |
| User entered '09:00'      | Lalicia Roman (b) (4) | 23 Apr 2021 17:07:16 |
|                           | (b) (4)               |                      |

**US3802168**

**Folder: Covid-19 Assessment 19 Apr 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:58:29**

[Date and Time of Contact \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Apr 2021 09:00' | System | 23 Apr 2021 17:07:16 |

US3802168

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:29

[Type of Contact](#)

| Audit                                    | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User signature succeeded.                | Judith Martin (b) (4)            | 23 Apr 2021 18:04:32 |
| User entered 'Safety Call (Safety Call)' | (b) (4)<br>Lalicia Roman (b) (4) | 23 Apr 2021 17:07:16 |

US3802168

Folder: Covid-19 Assessment 19 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:29

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 23 Apr 2021 18:04:32 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Lalicia Roman (b) (4) | 23 Apr 2021 17:07:16 |
|                           | (b) (4)               |                      |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:29

[Date of Contact](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:44 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered '26 Oct 2020' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:05:57 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:29

[Time of Contact](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 03 May 2021 20:48:44 |
| User signature succeeded. | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered '10:30'      | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:05:57 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:29

[Date and Time of Contact \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 May 2021 20:48:44 |
| User entered '26 Oct 2020 10:30' | System           | 26 Oct 2020 17:05:57 |



US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:29

[Type of Contact](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 03 May 2021 20:48:44 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:05:57 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:29

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 03 May 2021 20:48:44 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:05:57 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Symptom Day](#)

| Audit                        | User  | Time (GMT)           |
|------------------------------|---|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.    | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'Day 1 (Day 1)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Date](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered '26 Oct 2020' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Assessment Not Done](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded. | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered '0'          | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[O2 Saturation](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded. | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered '98'         | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 20:48:49 |
| User entered '%'  | System           | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Temperature](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded. | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered '98.4' F     | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:07:42 |



US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Chills](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Cough](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Shortness of Breath](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Difficulty Breathing](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Fatigue](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Body Aches](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Headache](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:07:42 |



US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[New Loss of Taste](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[New Loss of Smell](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Nasal Congestion](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Nausea](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Vomiting](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Diarrhea](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:07:42 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Sore Throat](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:07:42 |



US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Symptom Day](#)

| Audit                        | User  | Time (GMT)           |
|------------------------------|---|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.    | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'Day 2 (Day 2)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Date](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '27 Oct 2020' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Assessment Not Done](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded. | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered '0'          | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[O2 Saturation](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded. | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered '98'         | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 20:48:49 |
| User entered '%'  | System           | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Temperature](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '97.9' F     | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Chills](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Cough](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:45:14 |



US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Shortness of Breath](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Difficulty Breathing](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Fatigue](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Body Aches](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Headache](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[New Loss of Taste](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[New Loss of Smell](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:45:14 |



US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Nasal Congestion](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Nausea](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Vomiting](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Diarrhea](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Sore Throat](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:45:14 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Symptom Day](#)

| Audit                        | User  | Time (GMT)           |
|------------------------------|---|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.    | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'Day 3 (Day 3)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Date](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered '28 Oct 2020' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:46:35 |



US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Assessment Not Done](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded. | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered '0'          | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[O2 Saturation](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded. | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered '98'         | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 20:48:49 |
| User entered '%'  | System           | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Temperature](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded. | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered '98.1' F     | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Chills](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Cough](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Shortness of Breath](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Difficulty Breathing](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:46:35 |



US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Fatigue](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Body Aches](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Headache](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[New Loss of Taste](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[New Loss of Smell](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Nasal Congestion](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:46:35 |



US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Nausea](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Vomiting](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Diarrhea](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Sore Throat](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:48:49 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:46:35 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

[Date of Visit](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:56 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered '26 Oct 2020' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:08:30 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 03 May 2021 20:48:56 |
| User signature succeeded. | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:08:30 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 03 May 2021 20:48:56 |
| User signature succeeded.  | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| 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                | 29 Oct 2020 11:43:02 |
| User entered 'No (N)' reason for change: Data Entry Error                              | System                | 29 Oct 2020 11:43:02 |
| User opened query 'Data is required. Please complete.' (Site from System).             | Jennifer Nagg (b) (4) | 29 Oct 2020 11:43:02 |
| User entered empty.  | (b) (4)               |                      |
|  | System                | 26 Oct 2020 17:08:30 |
|  | Jennifer Nagg (b) (4) | 26 Oct 2020 17:08:30 |
|  | (b) (4)               |                      |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

[Date of Test](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:48:56 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered '26 Oct 2020' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:08:30 |



US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

[Type of Test Performed](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)              | 03 May 2021 20:48:56 |
| User signature succeeded.                                | Judith Martin (b) (4)         | 01 Feb 2021 16:26:07 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | (b) (4) Jennifer Nagg (b) (4) | 26 Oct 2020 17:08:30 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

[Other, specify](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 03 May 2021 20:48:56 |
| User signature succeeded. | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:08:30 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 03 May 2021 20:48:56 |
| User signature succeeded.                                 | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4)               | 29 Oct 2020 11:43:02 |
| User entered 'Yes (Y)'                                    | Jennifer Nagg (b) (4) | 26 Oct 2020 17:08:30 |
|   | (b) (4)               |                      |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

[Lab/ Institution Test Performed](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 03 May 2021 20:48:56 |
| User signature succeeded.   | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4)               | 29 Oct 2020 11:43:02 |
| User opened query 'Data is required. Please provide.' (Site from System). | System                | 26 Oct 2020 17:08:30 |
| User entered empty.   | Jennifer Nagg (b) (4) | 26 Oct 2020 17:08:30 |
|   | (b) (4)               |                      |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

[CLIA Certified?](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 03 May 2021 20:48:56 |
| User signature succeeded.   | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4)               | 29 Oct 2020 11:43:02 |
| User opened query 'Data is required. Please provide.' (Site from System). | System                | 26 Oct 2020 17:08:30 |
| User entered empty.   | Jennifer Nagg (b) (4) | 26 Oct 2020 17:08:30 |
|   | (b) (4)               |                      |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

COVID-19 Positive (CSA Programming Field Only)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 20:48:56 |
| User entered '0'  | System           | 29 Oct 2020 11:43:02 |

US3802168

Folder: Covid-19 Assessment 26 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:58:29

[Generate Next COVID-19 Assessment](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 03 May 2021 20:49:02 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 28 Jan 2021 14:24:18 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:29

[Date of Contact](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 03 May 2021 20:49:08 |
| User signature succeeded.   | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 30-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, data is missing in EDC. Kindly consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date (30DEC2020) and updating Swab data in the COVID Diagnostic Test form. Thank you.' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6)      | 19 Jan 2021 11:02:20 |
| Query 'Per GCL Lab Reconciliation: Swab: Sample dated 30-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, data is missing in EDC. Kindly consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date (30DEC2020) and updating Swab data in the COVID Diagnostic Test form. Thank you.' answered with 'entered' (Site from DM). | Jennifer Nagg (b) (4)<br>(b) (4) | 10 Jan 2021 11:15:18 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 30-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, data is missing in EDC. Kindly consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date (30DEC2020) and updating Swab data in the COVID Diagnostic Test form. Thank you.' (Site from DM).             | (b) (4), (b) (6)                 | 05 Jan 2021 07:40:18 |
| User entered '30 Dec 2020'  | Jamie Fries (b) (4)<br>(b) (4)   | 04 Jan 2021 18:29:28 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:29

[Time of Contact](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:08 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '09:52'      | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:29:28 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:29

[Date and Time of Contact \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 May 2021 20:49:08 |
| User entered '30 Dec 2020 09:52' | System           | 04 Jan 2021 18:29:28 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:29

[Type of Contact](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)               | 03 May 2021 20:49:08 |
| User signature succeeded.  | Judith Martin (b) (4)          | 01 Feb 2021 16:26:07 |
| User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' | (b) (4)<br>Jamie Fries (b) (4) | 04 Jan 2021 18:29:28 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:29

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:08 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:29:28 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Symptom Day](#)

| Audit                        | User                                      | Time (GMT)           |
|------------------------------|---|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.    | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Day 1 (Day 1)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Date](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '30 Dec 2020' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Assessment Not Done](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '0'          | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[O2 Saturation](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '100'        | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 20:49:15 |
| User entered '%'  | System           | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Temperature](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '98.1' F     | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Chills](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Cough](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Shortness of Breath](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Difficulty Breathing](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Fatigue](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Body Aches](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Headache](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[New Loss of Taste](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[New Loss of Smell](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Nasal Congestion](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Nausea](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Vomiting](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Diarrhea](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:29

[Sore Throat](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:32:20 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Symptom Day](#)

| Audit                        | User                                      | Time (GMT)           |
|------------------------------|---|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.    | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Day 2 (Day 2)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Date](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '31 Dec 2020' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Assessment Not Done](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '0'          | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[O2 Saturation](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '98'         | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 20:49:15 |
| User entered '%'  | System           | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Temperature](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '97.2' F     | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Chills](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Cough](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Shortness of Breath](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Difficulty Breathing](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Fatigue](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Body Aches](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Headache](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[New Loss of Taste](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[New Loss of Smell](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Nasal Congestion](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Nausea](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Vomiting](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Diarrhea](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:29

[Sore Throat](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:40:26 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Symptom Day](#)

| Audit                        | User                                      | Time (GMT)           |
|------------------------------|---|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.    | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Day 3 (Day 3)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Date](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '1 Jan 2021' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Assessment Not Done](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '0'          | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[O2 Saturation](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '97'         | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 20:49:15 |
| User entered '%'  | System           | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Temperature](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '98.1' F     | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Chills](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Cough](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Shortness of Breath](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Difficulty Breathing](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Fatigue](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Body Aches](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Headache](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[New Loss of Taste](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[New Loss of Smell](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Nasal Congestion](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Nausea](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Vomiting](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Diarrhea](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:29

[Sore Throat](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:42:23 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[Symptom Day](#)

| Audit                        | User                                      | Time (GMT)           |
|------------------------------|---|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.    | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Day 4 (Day 4)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[Date](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '2 Jan 2021' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[Assessment Not Done](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '0'          | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[O2 Saturation](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '98'         | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 20:49:15 |
| User entered '%'  | System           | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[Temperature](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '97.6' F     | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[Chills](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[Cough](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[Shortness of Breath](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[Difficulty Breathing](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[Fatigue](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[Body Aches](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[Headache](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[New Loss of Taste](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[New Loss of Smell](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[Nasal Congestion](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[Nausea](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[Vomiting](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[Diarrhea](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:29

[Sore Throat](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:44:06 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[Symptom Day](#)

| Audit                        | User                                      | Time (GMT)           |
|------------------------------|---|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.    | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Day 5 (Day 5)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[Date](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '3 Jan 2021' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[Assessment Not Done](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '0'          | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[O2 Saturation](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '99'         | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 20:49:15 |
| User entered '%'  | System           | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[Temperature](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '97.7' F     | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[Chills](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[Cough](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[Shortness of Breath](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[Difficulty Breathing](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[Fatigue](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[Body Aches](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[Headache](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[New Loss of Taste](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[New Loss of Smell](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[Nasal Congestion](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[Nausea](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[Vomiting](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[Diarrhea](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:29

[Sore Throat](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 04 Jan 2021 18:46:35 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[Symptom Day](#)

| Audit                        | User                                       | Time (GMT)           |
|------------------------------|--|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                           | 03 May 2021 20:49:15 |
| User signature succeeded.    | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'Day 6 (Day 6)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[Date](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered '4 Jan 2021' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[Assessment Not Done](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)           | 01 Feb 2021 16:26:07 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4) | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[O2 Saturation](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered '99'         | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 20:49:15 |
| User entered '%'  | System           | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[Temperature](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 03 May 2021 20:49:15 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered '97.6' F     | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Jan 2021 21:13:51 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[Chills](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[Cough](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)           | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Emily Carney (b) (4) | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[Shortness of Breath](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[Difficulty Breathing](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[Fatigue](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)           | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Emily Carney (b) (4) | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[Body Aches](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[Headache](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Jan 2021 21:13:51 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[New Loss of Taste](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[New Loss of Smell](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[Nasal Congestion](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'Mild (Mild)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[Nausea](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[Vomiting](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[Diarrhea](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Jan 2021 21:13:51 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:29

[Sore Throat](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 03 May 2021 20:49:15 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'None (None)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Jan 2021 21:13:51 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

[Date of Visit](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 May 2021 20:49:25 |
| User signature succeeded.  | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered '30 Dec 2020' | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 10 Jan 2021 10:37:56 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 03 May 2021 20:49:25 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jennifer Nagg (b) (4) | 10 Jan 2021 10:37:56 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 03 May 2021 20:49:25 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'No (N)'     | (b) (4)<br>Jennifer Nagg (b) (4) | 10 Jan 2021 10:37:56 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

[Date of Test](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 May 2021 20:49:25 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '30 Dec 2020' | (b) (4)<br>Jennifer Nagg (b) (4) | 10 Jan 2021 10:37:56 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

[Type of Test Performed](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)              | 03 May 2021 20:49:25 |
| User signature succeeded.                                | Judith Martin (b) (4)         | 01 Feb 2021 16:26:07 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | (b) (4) Jennifer Nagg (b) (4) | 10 Jan 2021 10:37:56 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

[Other, specify](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 03 May 2021 20:49:25 |
| User signature succeeded. | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 10 Jan 2021 10:37:56 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 03 May 2021 20:49:25 |
| User signature succeeded. | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered 'No (N)'     | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 10 Jan 2021 10:37:56 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

[Lab/ Institution Test Performed](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 03 May 2021 20:49:25 |
| User signature succeeded. | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 10 Jan 2021 10:37:56 |



US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

[CLIA Certified?](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 03 May 2021 20:49:25 |
| User signature succeeded. | Judith Martin (b) (4)                       | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4)<br>(b) (4) | 10 Jan 2021 10:37:56 |

US3802168

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:29

COVID-19 Positive (CSA Programming Field Only)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 20:49:25 |
| User entered '0'  | System           | 10 Jan 2021 10:37:56 |

**US3802168**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Visit](#)

| Audit                                       | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.                           | (b) (4), (b) (6)                 | 02 May 2021 09:14:48 |
| User accepted default value 'Day 3 (Day 3)' | Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:48:10 |

US3802168

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:58:29

[Was Saliva Collected?](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 02 May 2021 09:14:48 |
| User closed query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' (Site from DM).   |                                  | 24 Feb 2021 07:25:38 |
| Query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' answered with 'Updated because saliva was not collected.' (Site from DM). | Emily Carney (b) (4)<br>(b) (4)  | 17 Feb 2021 21:14:03 |
| User opened query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' (Site from DM).   | (b) (4), (b) (6)                 | 10 Feb 2021 11:58:14 |
| User signature succeeded.   | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:07 |
| User entered 'NA (COVID-19 Negative) (NA)'  | Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:48:10 |

US3802168

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:58:29

[Date of Collection](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 02 May 2021 09:14:48 |
| User signature succeeded.                              | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
| Signature has been broken.                             | Emily Carney (b) (4)  | 17 Feb 2021 21:13:44 |
| User entered empty; reason for change Data Entry Error | Emily Carney (b) (4)  | 17 Feb 2021 21:13:44 |
| User signature succeeded.                              | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User entered '28 Oct 2020'                             | Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:10 |

**US3802168**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Visit](#)

| Audit                                       | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.                           | (b) (4), (b) (6)                 | 02 May 2021 09:14:48 |
| User accepted default value 'Day 5 (Day 5)' | Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:48:10 |

US3802168

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:58:29

[Was Saliva Collected?](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 02 May 2021 09:14:48 |
| User signature succeeded.  | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)               | 29 Oct 2020 11:48:41 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 29 Oct 2020 11:48:41 |
| User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error         | Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:41 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)               | 29 Oct 2020 11:48:10 |
| User entered empty.  | System                | 29 Oct 2020 11:48:10 |
|  | Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:10 |
|  | (b) (4)               |                      |

**US3802168**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Date of Collection](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 02 May 2021 09:14:48 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:10 |



**US3802168**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Visit](#)

| Audit                                       | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.                           | (b) (4), (b) (6)                 | 02 May 2021 09:14:48 |
| User accepted default value 'Day 7 (Day 7)' | Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:48:10 |

US3802168

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:58:29

[Was Saliva Collected?](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 02 May 2021 09:14:48 |
| User signature succeeded.  | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)               | 29 Oct 2020 11:48:41 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 29 Oct 2020 11:48:41 |
| User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error         | Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:41 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)               | 29 Oct 2020 11:48:10 |
| User entered empty.  | System                | 29 Oct 2020 11:48:10 |
|  | Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:10 |
|  | (b) (4)               |                      |

**US3802168**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Date of Collection](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 02 May 2021 09:14:48 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:10 |

**US3802168**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Visit](#)

| Audit                                       | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.                           | (b) (4), (b) (6)                 | 02 May 2021 09:14:48 |
| User accepted default value 'Day 9 (Day 9)' | Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:48:10 |

US3802168

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:58:29

[Was Saliva Collected?](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 02 May 2021 09:14:48 |
| User signature succeeded.  | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)               | 29 Oct 2020 11:48:41 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 29 Oct 2020 11:48:41 |
| User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error         | Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:41 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)               | 29 Oct 2020 11:48:10 |
| User entered empty.  | System                | 29 Oct 2020 11:48:10 |
|  | Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:10 |
|  | (b) (4)               |                      |

**US3802168**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Date of Collection](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 02 May 2021 09:14:48 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:10 |

**US3802168**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Visit](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.                             | (b) (4), (b) (6)                 | 02 May 2021 09:14:48 |
| User accepted default value 'Day 14 (Day 14)' | Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:48:10 |

US3802168

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:58:29

[Was Saliva Collected?](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 02 May 2021 09:14:48 |
| User signature succeeded.  | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)               | 29 Oct 2020 11:48:41 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 29 Oct 2020 11:48:41 |
| User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error         | Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:41 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)               | 29 Oct 2020 11:48:10 |
| User entered empty.  | System                | 29 Oct 2020 11:48:10 |
|  | Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:10 |
|  | (b) (4)               |                      |



**US3802168**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Date of Collection](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 02 May 2021 09:14:48 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:10 |

**US3802168**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Visit](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.                             | (b) (4), (b) (6)                 | 02 May 2021 09:14:48 |
| User accepted default value 'Day 21 (Day 21)' | Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:48:10 |

US3802168

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:58:29

[Was Saliva Collected?](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 02 May 2021 09:14:48 |
| User signature succeeded.  | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)               | 29 Oct 2020 11:48:41 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 29 Oct 2020 11:48:41 |
| User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error         | Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:41 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)               | 29 Oct 2020 11:48:10 |
| User entered empty.  | System                | 29 Oct 2020 11:48:10 |
|  | Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:10 |
|  | (b) (4)               |                      |

**US3802168**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Date of Collection](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 02 May 2021 09:14:48 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:10 |

**US3802168**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:58:29**

[Visit](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.                             | (b) (4), (b) (6)                 | 02 May 2021 09:14:48 |
| User accepted default value 'Day 28 (Day 28)' | Jennifer Nagg (b) (4)<br>(b) (4) | 29 Oct 2020 11:48:10 |

US3802168

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:58:29

[Was Saliva Collected?](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 02 May 2021 09:14:48 |
| User signature succeeded.  | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| 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                | 29 Oct 2020 11:48:41 |
| User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error         | System                | 29 Oct 2020 11:48:41 |
| User opened query 'Data is required. Please complete.' (Site from System).             | Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:41 |
| User entered empty.  | (b) (4)               |                      |
|  | System                | 29 Oct 2020 11:48:10 |
|  | Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:10 |
|  | (b) (4)               |                      |

**US3802168**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:58:29**

[Date of Collection](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 02 May 2021 09:14:48 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:48:10 |

**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Visit](#)

| Audit                                       | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | Jennifer Nagg (b) (4)<br>(b) (4) | 10 Jan 2021 10:38:40 |



**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Was Saliva Collected?](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User signature succeeded.                  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4)<br>Jennifer Nagg (b) (4) | 10 Jan 2021 10:38:40 |

**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Date of Collection](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 10 Jan 2021 10:38:40 |

**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Visit](#)

| Audit                                       | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | Jennifer Nagg (b) (4)<br>(b) (4) | 10 Jan 2021 10:38:40 |

**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Was Saliva Collected?](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User signature succeeded.                  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4)<br>Jennifer Nagg (b) (4) | 10 Jan 2021 10:38:40 |

**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Date of Collection](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 10 Jan 2021 10:38:40 |

**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Visit](#)

| Audit                                       | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | Jennifer Nagg (b) (4)<br>(b) (4) | 10 Jan 2021 10:38:40 |

**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Was Saliva Collected?](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User signature succeeded.                  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4)<br>Jennifer Nagg (b) (4) | 10 Jan 2021 10:38:40 |

**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Date of Collection](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 10 Jan 2021 10:38:40 |



**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Visit](#)

| Audit                                       | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | Jennifer Nagg (b) (4)<br>(b) (4) | 10 Jan 2021 10:38:40 |

**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Was Saliva Collected?](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User signature succeeded.                  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4)<br>Jennifer Nagg (b) (4) | 10 Jan 2021 10:38:40 |

**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Date of Collection](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 10 Jan 2021 10:38:40 |

**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Visit](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | Jennifer Nagg (b) (4)<br>(b) (4) | 10 Jan 2021 10:38:40 |

**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Was Saliva Collected?](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User signature succeeded.                  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4)<br>Jennifer Nagg (b) (4) | 10 Jan 2021 10:38:40 |

**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Date of Collection](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 10 Jan 2021 10:38:40 |

**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Visit](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | Jennifer Nagg (b) (4)<br>(b) (4) | 10 Jan 2021 10:38:40 |

**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Was Saliva Collected?](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User signature succeeded.                  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4)<br>Jennifer Nagg (b) (4) | 10 Jan 2021 10:38:40 |



**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Date of Collection](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 10 Jan 2021 10:38:40 |

**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:58:29**

[Visit](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | Jennifer Nagg (b) (4)<br>(b) (4) | 10 Jan 2021 10:38:40 |

**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:58:29**

[Was Saliva Collected?](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User signature succeeded.                  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4)<br>Jennifer Nagg (b) (4) | 10 Jan 2021 10:38:40 |

**US3802168**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:58:29**

[Date of Collection](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 10 Jan 2021 10:38:40 |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Was this visit performed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 02 May 2021 09:14:20 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:09:50 |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 02 May 2021 09:14:20 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '26 Oct 2020' | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:09:50 |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 02 May 2021 09:14:20 |
| User signature succeeded.      | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User entered 'Clinic (Clinic)' | Jennifer Nagg (b) (4) | 26 Oct 2020 17:09:50 |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 02 May 2021 09:14:20 |
| User entered 'SICKD1' | System           | 26 Oct 2020 17:09:50 |



US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Were vital signs assessed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 02 May 2021 09:14:27 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:11:45 |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 02 May 2021 09:14:27 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '26 Oct 2020' | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:11:45 |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 02 May 2021 09:14:27 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '10:30'      | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:11:45 |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 02 May 2021 09:14:27 |
| User entered '26 Oct 2020 10:30' | System           | 26 Oct 2020 17:11:45 |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Height (xxx.x)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 02 May 2021 09:14:27 |
| User signature succeeded.   | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| Query 'Per CDM: Per page 25 of CCGs version 2.0 and per page 119 of Protocol, "HEIGHT" and "WEIGHT" are to be captured on Illness Visit Day 1. Please review and update accordingly. Thankyou.' canceled (Site from DM).  | (b) (4)<br>(b) (4), (b) (6)      | 19 Nov 2020 17:40:15 |
| User opened query 'Per CDM: Per page 25 of CCGs version 2.0 and per page 119 of Protocol, "HEIGHT" and "WEIGHT" are to be captured on Illness Visit Day 1. Please review and update accordingly. Thankyou.' (Site from DM).   | (b) (4), (b) (6)                 | 19 Nov 2020 08:41:42 |
| User closed query 'Per CDM: Per page 25 of CCGs version 2.0, "HEIGHT" and "WEIGHT" are to be captured on Illness Visit Day 1. Please review and reconcile, else clarify. Thank you.' (Site from DM).  | (b) (4), (b) (6)                 | 19 Nov 2020 08:38:01 |
| DataPoint Un-verified.  | (b) (4), (b) (6)                 | 10 Nov 2020 18:45:14 |
| DataPoint Verified.   | (b) (4), (b) (6)                 | 10 Nov 2020 18:45:08 |
| Query 'Per CDM: Per page 25 of CCGs version 2.0, "HEIGHT" and "WEIGHT" are to be captured on Illness Visit Day 1. Please review and reconcile, else clarify. Thank you.<br>' answered with 'Per page 119 of protocol, height and weight are not part of illness visit targeted physical exam' (Site from DM). | Jennifer Nagg (b) (4)<br>(b) (4) | 06 Nov 2020 20:00:34 |
| User opened query 'Per CDM: Per page 25 of CCGs version 2.0, "HEIGHT" and "WEIGHT" are to be captured on Illness Visit Day 1. Please review and reconcile, else clarify. Thank you.' (Site from DM).  | (b) (4), (b) (6)                 | 02 Nov 2020 10:28:18 |
| Data hard unlocked.   | (b) (4), (b) (6)                 | 02 Nov 2020 10:28:14 |
| Data hard locked.   | (b) (4), (b) (6)                 | 02 Nov 2020 10:28:12 |
| User entered missing code ND - Not Done.  | Jennifer Nagg (b) (4)<br>(b) (4) | 26 Oct 2020 17:11:45 |
| DataPoint set to visible.   | System                           | 26 Oct 2020 17:09:50 |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Weight (xxx.x)

| Audit                                    | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                 | 02 May 2021 09:14:27 |
| User signature succeeded.                | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered missing code ND - Not Done. | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:11:45 |
| DataPoint set to visible.                | (b) (4)<br>System                | 26 Oct 2020 17:09:50 |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Temperature (xxx.x)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 02 May 2021 09:14:27 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '98.4' F     | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:11:45 |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Route of measurement](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                 | 02 May 2021 09:14:27 |
| User signature succeeded.    | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Other (Other)' | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:11:45 |



**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[If Other, specify](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 02 May 2021 09:14:27 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'infared'    | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:11:45 |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Pulse \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 02 May 2021 09:14:27 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '80'         | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:11:45 |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 02 May 2021 09:14:27 |
| User entered 'bpm' | System           | 26 Oct 2020 17:11:45 |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 02 May 2021 09:14:27 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '20'         | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:11:45 |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 02 May 2021 09:14:27 |
| User entered 'breaths/min' | System           | 26 Oct 2020 17:11:45 |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Systolic Blood Pressure (xxx)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 02 May 2021 09:14:27 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '149'        | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:11:45 |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:14:27 |
| User entered 'mmHg' | System           | 26 Oct 2020 17:11:45 |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 02 May 2021 09:14:27 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '82'         | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:11:45 |



**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 09:14:27 |
| User entered 'mmHg' | System           | 26 Oct 2020 17:11:45 |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 09:14:27 |
|                   |                  |                      |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 09:14:27 |
|                   |                  |                      |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:58:29**

[Was the physical examination performed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 02 May 2021 09:14:34 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:26:33 |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:58:29**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 02 May 2021 09:14:34 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '26 Oct 2020' | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:26:33 |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:58:29

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 02 May 2021 09:14:41 |
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:26:44 |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:58:29**

[Date of Collection](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 02 May 2021 09:14:41 |
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '26 Oct 2020' | (b) (4)<br>Jennifer Nagg (b) (4) | 26 Oct 2020 17:26:44 |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:29

[Was this visit performed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lalicia Roman (b) (4) | 30 Dec 2020 16:49:36 |
|                           | (b) (4)                          |                      |



**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '30 Dec 2020' | (b) (4)<br>Lalicia Roman (b) (4) | 30 Dec 2020 16:49:36 |
|                            | (b) (4)                          |                      |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:29

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| User signature succeeded.      | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Lalicia Roman (b) (4) | 30 Dec 2020 16:49:36 |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'SICKD1' | System | 30 Dec 2020 16:49:36 |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Were vital signs assessed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lalicia Roman (b) (4) | 30 Dec 2020 16:50:39 |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
|                            | (b) (4)               |                      |
| User entered '30 Dec 2020' | Lalicia Roman (b) (4) | 30 Dec 2020 16:50:39 |
|                            | (b) (4)               |                      |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Time of assessment (00:00-23:59)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| User signature succeeded.                                | Judith Martin (b) (4) | 03 Mar 2021 16:35:06 |
|  | (b) (4)               |                      |
| Signature has been broken.                               | Lalicia Roman (b) (4) | 25 Feb 2021 18:49:06 |
|  | (b) (4)               |                      |
| User entered '09:54' reason for change: Data Entry Error | Lalicia Roman (b) (4) | 25 Feb 2021 18:49:06 |
|  | (b) (4)               |                      |
| User signature succeeded.                                | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
|  | (b) (4)               |                      |
| User entered '09:24'                                     | Lalicia Roman (b) (4) | 30 Dec 2020 16:50:39 |
|  | (b) (4)               |                      |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Dec 2020 09:54' | System | 25 Feb 2021 18:49:06 |
| User entered '30 Dec 2020 09:24' | System | 30 Dec 2020 16:50:39 |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Height (xxx.x)

| Audit                                    | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| User signature succeeded.                | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
|  | (b) (4)               |                      |
| User entered missing code ND - Not Done. | Lalicia Roman (b) (4) | 30 Dec 2020 16:50:39 |
|  | (b) (4)               |                      |
| DataPoint set to visible.                | System                | 30 Dec 2020 16:49:36 |



**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Weight \(xxx.x\)](#)

| Audit                                    | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User signature succeeded.                | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered missing code ND - Not Done. | (b) (4)<br>Lalicia Roman (b) (4) | 30 Dec 2020 16:50:39 |
| DataPoint set to visible.                | (b) (4)<br>System                | 30 Dec 2020 16:49:36 |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Temperature (xxx.x)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '98.1' F     | (b) (4)<br>Lalicia Roman (b) (4) | 30 Dec 2020 16:50:39 |
|                           | (b) (4)                          |                      |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Route of measurement](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| User signature succeeded.    | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Other (Other)' | (b) (4)<br>Lalicia Roman (b) (4) | 30 Dec 2020 16:50:39 |
|                              | (b) (4)                          |                      |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[If Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
|                           | (b) (4)               |                      |
| User entered 'infrared'   | Lalicia Roman (b) (4) | 30 Dec 2020 16:50:39 |
|                           | (b) (4)               |                      |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Pulse \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '68'         | (b) (4)<br>Lalicia Roman (b) (4) | 30 Dec 2020 16:50:39 |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 30 Dec 2020 16:50:39 |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '18'         | (b) (4)<br>Lalicia Roman (b) (4) | 30 Dec 2020 16:50:39 |
|                           | (b) (4)                          |                      |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 30 Dec 2020 16:50:39 |



US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Systolic Blood Pressure (xxx)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '169'        | (b) (4)<br>Lalicia Roman (b) (4) | 30 Dec 2020 16:50:39 |
|                           | (b) (4)                          |                      |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 30 Dec 2020 16:50:39 |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:29

Diastolic Blood Pressure (xxx)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '89'         | (b) (4)<br>Lalicia Roman (b) (4) | 30 Dec 2020 16:50:39 |
|                           | (b) (4)                          |                      |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 30 Dec 2020 16:50:39 |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:58:29**

[Was the physical examination performed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lalicia Roman (b) (4) | 30 Dec 2020 16:50:50 |

US3802168

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:29

Date of examination (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
|                            | (b) (4)               |                      |
| User entered '30 Dec 2020' | Lalicia Roman (b) (4) | 30 Dec 2020 16:50:50 |
|                            | (b) (4)               |                      |

US3802168

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:58:29**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lalicia Roman (b) (4) | 30 Dec 2020 16:51:07 |

**US3802168**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:58:29**

[Date of Collection](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered '30 Dec 2020' | (b) (4)<br>Lalicia Roman (b) (4) | 30 Dec 2020 16:51:07 |
|                            | (b) (4)                          |                      |



**US3802168**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Was this visit performed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered 'No (N)'     | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:47:17 |

US3802168

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:29

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
|                           | (b) (4)               |                      |
| User entered empty.       | Jennifer Nagg (b) (4) | 29 Oct 2020 11:47:17 |
|                           | (b) (4)               |                      |

US3802168

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:29

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 29 Oct 2020 11:47:17 |

**US3802168**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Folder OID](#)

| Audit                  | User   | Time (GMT)           |
|------------------------|--------|----------------------|
| User entered 'SICKD28' | System | 29 Oct 2020 11:47:17 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Was this visit performed?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:31:31 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:29

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '5 Jan 2021' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:31:31 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                                      | Time (GMT)           |
|--------------------------------|---|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded.      | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:31:31 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Folder OID](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 28 Apr 2021 21:40:16 |
| User entered 'UNBLND_DECIDE' | System           | 05 Jan 2021 22:31:31 |



**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:58:29**

[Date of updated informed consent \(dd MMM yyyy\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '5 Jan 2021' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:32:51 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:58:29**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit                                      | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                | 28 Apr 2021 21:40:16 |
| User signature succeeded.                  | Judith Martin (b) (4)           | 08 Apr 2021 18:40:53 |
| User entered '0'                           | (b) (4)<br>Emily Carney (b) (4) | 08 Apr 2021 18:28:16 |
| Amendment Manager inserted this DataPoint. | (b) (4)<br>System               | 06 Mar 2021 18:48:33 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:58:29**

[Was the participant unblinded?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:32:51 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:58:29

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 28 Apr 2021 21:40:16 |
| User closed query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).             |                                 | 16 Apr 2021 01:53:11 |
| User signature succeeded.  | Judith Martin (b) (4)           | 08 Apr 2021 18:40:53 |
| Query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'updated' (Site from DM). | (b) (4)<br>Emily Carney (b) (4) | 08 Apr 2021 18:28:44 |
| User entered 'Amendment 6 or later (Amendment 6 or later)'   | Emily Carney (b) (4)            | 08 Apr 2021 18:28:16 |
| User opened query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).             | (b) (4), (b) (6)                | 08 Apr 2021 11:07:25 |
| Amendment Manager inserted this DataPoint.   | System                          | 06 Mar 2021 18:48:33 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:58:29

Date of unblinding (*dd MMM yyyy*)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '5 Jan 2021' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:32:51 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:58:29

[Participant randomization assignment](#)

| Audit                            | User                                      | Time (GMT)           |
|----------------------------------|---|----------------------|
| Data hard locked.                | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded.        | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Placebo (Placebo)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:32:51 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:58:29**

[Actual Dose 1](#)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6)               | 28 Apr 2021 21:40:16 |
| User signature succeeded.                           | Judith Martin (b) (4)          | 01 Feb 2021 16:26:07 |
| Amendment Manager: User entered 'Placebo (Placebo)' | (b) (4)<br>System              | 20 Jan 2021 14:21:53 |
| User entered 'Placebo (Placebo)'                    | Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:32:51 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:58:29

[Actual Dose 2](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6)      | 28 Apr 2021 21:40:16 |
| User signature succeeded.                           | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| Amendment Manager: User entered 'Placebo (Placebo)' | (b) (4)               | 20 Jan 2021 14:21:53 |
| User entered 'Placebo (Placebo)'                    | Jamie Fries (b) (4)   | 05 Jan 2021 22:32:51 |
|   | (b) (4)               |                      |



US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:58:29

[Will participant receive mRNA-1273?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:32:51 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:58:29**

[Placebo Only Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:40:16 |
| User entered '1'  | System           | 05 Jan 2021 22:32:51 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:58:29**

[Continuing with mRNA-1273](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:40:16 |
| User entered 'I'  | System           | 05 Jan 2021 22:32:51 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:29

Height

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '177.2' cm   | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:36:45 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:29

[Weight](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '243' lb     | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:36:45 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:29

BMI (xxx.x)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 21:40:16 |
| User entered '35.17679'   | System           | 05 Jan 2021 22:36:45 |
| DataPoint set to visible. | System           | 05 Jan 2021 22:32:51 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:29

Height

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '177.2' cm   | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:36:45 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:29

[Weight](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '243' lb     | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:36:45 |



US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:29

BMI (xxx.x)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 21:40:16 |
| User entered '35.17679'   | System           | 05 Jan 2021 22:36:45 |
| DataPoint set to visible. | System           | 05 Jan 2021 22:32:51 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Timepoint](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)               | 28 Apr 2021 21:40:16 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:36:45 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Were vital signs assessed?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:36:45 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '5 Jan 2021' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:36:45 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '16:08'      | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:36:45 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 28 Apr 2021 21:40:16 |
| User entered '5 Jan 2021 16:08' | System           | 05 Jan 2021 22:36:45 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

Temperature (xxx.x)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 28 Apr 2021 21:40:16 |
| User signature succeeded.   | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4)               |                      |
| User entered '97.8' F reason for change: Data Entry Error                               | System                | 05 Jan 2021 22:38:49 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | Jamie Fries (b) (4)   | 05 Jan 2021 22:38:49 |
| User entered '97.8f' (non-conformant).  | (b) (4)               |                      |
|   | System                | 05 Jan 2021 22:36:45 |
|   | Jamie Fries (b) (4)   | 05 Jan 2021 22:36:45 |
|   | (b) (4)               |                      |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Route of measurement](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 28 Apr 2021 21:40:16 |
| User signature succeeded.  | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4)               | 05 Jan 2021 22:39:09 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System                | 05 Jan 2021 22:39:09 |
| User entered 'Other (Other)' reason for change: Data Entry Error                             | Jamie Fries (b) (4)   | 05 Jan 2021 22:39:09 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | (b) (4)               | 05 Jan 2021 22:38:49 |
| User entered empty.  | Jamie Fries (b) (4)   | 05 Jan 2021 22:36:45 |
|  | (b) (4)               |                      |



US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[If Other, specify](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 28 Apr 2021 21:40:16 |
| User signature succeeded.                                   | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User entered 'infrared' reason for change: Data Entry Error | (b) (4)               |                      |
|   | Jamie Fries (b) (4)   | 05 Jan 2021 22:39:09 |
| User entered empty.   | (b) (4)               |                      |
|   | Jamie Fries (b) (4)   | 05 Jan 2021 22:36:45 |
|   | (b) (4)               |                      |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Pulse \(xxx\)](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 28 Apr 2021 21:40:16 |
| User signature succeeded.  | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4)               | 05 Jan 2021 22:38:49 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System                | 05 Jan 2021 22:38:49 |
| User entered '78' reason for change: Data Entry Error  | Jamie Fries (b) (4)   | 05 Jan 2021 22:38:49 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | (b) (4)               | 05 Jan 2021 22:36:45 |
| User entered empty.  | System                | 05 Jan 2021 22:36:45 |
|  | Jamie Fries (b) (4)   | 05 Jan 2021 22:36:45 |
|  | (b) (4)               |                      |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:40:16 |
| User entered 'bpm'  | System           | 05 Jan 2021 22:38:49 |
| User entered empty. | System           | 05 Jan 2021 22:36:45 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate \(xxx\)](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 28 Apr 2021 21:40:16 |
| User signature succeeded.  | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4)               | 05 Jan 2021 22:38:49 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System                | 05 Jan 2021 22:38:49 |
| User entered '17' reason for change: Data Entry Error  | Jamie Fries (b) (4)   | 05 Jan 2021 22:38:49 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | (b) (4)               | 05 Jan 2021 22:36:45 |
| User entered empty.  | System                | 05 Jan 2021 22:36:45 |
|  | Jamie Fries (b) (4)   | 05 Jan 2021 22:36:45 |
|  | (b) (4)               |                      |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 21:40:16 |
| User entered 'breaths/min' | System           | 05 Jan 2021 22:38:49 |
| User entered empty.        | System           | 05 Jan 2021 22:36:45 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

Systolic Blood Pressure (xxx)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 28 Apr 2021 21:40:16 |
| User signature succeeded.   | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4)               |                      |
| Query 'Data is required. Please provide.' answered by System              | System                | 05 Jan 2021 22:38:49 |
| data change (Site from System).   |                       | 05 Jan 2021 22:38:49 |
| User entered '135' reason for change: Data Entry Error                    | Jamie Fries (b) (4)   | 05 Jan 2021 22:38:49 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4)               |                      |
| User entered empty.   | System                | 05 Jan 2021 22:36:45 |
|   | Jamie Fries (b) (4)   | 05 Jan 2021 22:36:45 |
|   | (b) (4)               |                      |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:40:16 |
| User entered 'mmHg' | System           | 05 Jan 2021 22:38:49 |
| User entered empty. | System           | 05 Jan 2021 22:36:45 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Diastolic Blood Pressure \(xxx\)](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 28 Apr 2021 21:40:16 |
| User signature succeeded.  | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4)               |                      |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System                | 05 Jan 2021 22:38:49 |
| User entered '89' reason for change: Data Entry Error  | Jamie Fries (b) (4)   | 05 Jan 2021 22:38:49 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | (b) (4)               |                      |
| User entered empty.  | System                | 05 Jan 2021 22:36:45 |
|  | Jamie Fries (b) (4)   | 05 Jan 2021 22:36:45 |
|  | (b) (4)               |                      |



**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:40:16 |
| User entered 'mmHg' | System           | 05 Jan 2021 22:38:49 |
| User entered empty. | System           | 05 Jan 2021 22:36:45 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:29

Height

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '177.2' cm   | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:36:45 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:29

[Weight](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '243' lb     | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:36:45 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:29

BMI (xxx.x)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 21:40:16 |
| User entered '35.17679'   | System           | 05 Jan 2021 22:36:45 |
| DataPoint set to visible. | System           | 05 Jan 2021 22:32:51 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Timepoint](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)               | 28 Apr 2021 21:40:16 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:42:01 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Were vital signs assessed?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:42:01 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '5 Jan 2021' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:42:01 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

Time of assessment (00:00-23:59)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '17:25'      | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:42:01 |



**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 28 Apr 2021 21:40:16 |
| User entered '5 Jan 2021 17:25' | System           | 05 Jan 2021 22:42:01 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

Temperature (xxx.x)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '97.0' F     | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:42:01 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Route of measurement](#)

| Audit                        | User                                      | Time (GMT)           |
|------------------------------|---|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded.    | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Other (Other)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:42:01 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[If Other, specify](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'infrared'   | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:42:01 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Pulse \(xxx\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '82'         | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:42:01 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 21:40:16 |
| User entered 'bpm' | System           | 05 Jan 2021 22:42:01 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '18'         | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:42:01 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 21:40:16 |
| User entered 'breaths/min' | System           | 05 Jan 2021 22:42:01 |



US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '140'        | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:42:01 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:40:16 |
| User entered 'mmHg' | System           | 05 Jan 2021 22:42:01 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '90'         | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:42:01 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:40:16 |
| User entered 'mmHg' | System           | 05 Jan 2021 22:42:01 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:58:29**

[Was the physical examination performed?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:39:39 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:29

Date of examination (dd MMM yyyy)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:16 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '5 Jan 2021' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:39:39 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

[Was study treatment given?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:40:42 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

[If No, reason not given](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:40:42 |



US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:40:42 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:58:29**

[What was the study treatment? \(Unblinded\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered 'mRNA-1273'  | System           | 05 Jan 2021 22:40:42 |
| DataPoint set to visible. | System           | 05 Jan 2021 22:32:51 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

What was the treatment date? (dd MMM yyyy)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '5 Jan 2021' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:40:42 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '16:51'      | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:40:42 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:58:29**

[Treatment Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered '5 Jan 2021 16:51' | System           | 05 Jan 2021 22:40:42 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

[Which arm was used to give treatment?](#)

| Audit                              | User                                      | Time (GMT)           |
|------------------------------------|---|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:14 |
| User signature succeeded.          | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:40:42 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

What was the frequency of the study treatment dosing?

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered 'ONCE' | System           | 05 Jan 2021 22:40:42 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:58:29**

[What was the route of administration for the study treatment?](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered 'INTRAMUSCULAR' | System           | 05 Jan 2021 22:40:42 |



US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:29

[Was the sample collected?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:33:16 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:29

Collection date (dd MMM yyyy)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)               | 28 Apr 2021 21:40:14 |
| User signature succeeded.  | Judith Martin (b) (4)          | 01 Feb 2021 16:26:07 |
| Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 05JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 05JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' canceled (Site from DM).    | (b) (4)<br>(b) (4), (b) (6)    | 14 Jan 2021 13:21:16 |
| User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 05JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 05JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' (Site from DM). | (b) (4), (b) (6)               | 13 Jan 2021 19:28:16 |
| User entered '5 Jan 2021'  | Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:33:16 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:29

Collection time (00:00-23:59)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '16:45'      | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:33:16 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:58:29**

[Collection date and time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered '5 Jan 2021 16:45' | System           | 05 Jan 2021 22:33:16 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:58:29**

[Was the sample collected?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:33:47 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:58:29**

[Collection date \(dd MMM yyyy\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '5 Jan 2021' | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:33:47 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:58:29**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered '16:47'      | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:33:47 |

**US3802168**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:58:29**

[Collection Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered '5 Jan 2021 16:47' | System           | 05 Jan 2021 22:33:47 |



US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:29

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)                     | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jamie Fries (b) (4)<br>(b) (4) | 05 Jan 2021 22:34:00 |

US3802168

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:29

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered 'I'  | System           | 05 Jan 2021 22:34:00 |

**US3802168**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Was Contact Attempted?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 30 Apr 2021 18:24:12 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 12 Jan 2021 16:05:31 |

**US3802168**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 30 Apr 2021 18:24:12 |
| User signature succeeded.  | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered '12 Jan 2021' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 12 Jan 2021 16:05:31 |

**US3802168**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                | 30 Apr 2021 18:24:12 |
| User signature succeeded.                  | Judith Martin (b) (4)           | 01 Feb 2021 16:26:14 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Emily Carney (b) (4) | 12 Jan 2021 16:05:31 |

US3802168

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:29

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 30 Apr 2021 18:24:12 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 12 Jan 2021 16:05:31 |

US3802168

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:29

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 30 Apr 2021 18:24:12 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 12 Jan 2021 16:05:35 |

**US3802168**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 18:24:12 |
|                   |                  |                      |
| User entered 'I'  | System           | 12 Jan 2021 16:05:35 |



**US3802168**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[OLD29 Placebo Flag](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 30 Apr 2021 18:24:12 |
|                           |                  |                      |
| User entered 'I'          | System           | 12 Jan 2021 16:05:35 |
| DataPoint set to visible. | System           | 12 Jan 2021 16:05:35 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Was this visit performed?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)           | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 01 Feb 2021 14:24:23 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered '1 Feb 2021' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 01 Feb 2021 14:24:23 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                                       | Time (GMT)           |
|--------------------------------|--|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                           | 28 Apr 2021 21:40:14 |
| User signature succeeded.      | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 01 Feb 2021 14:24:23 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Folder OID](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered 'OLD29' | System           | 01 Feb 2021 14:24:23 |

US3802168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Timepoint](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)                | 28 Apr 2021 21:40:14 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Emily Carney (b) (4)<br>(b) (4) | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Were vital signs assessed?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)           | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:29**

**Date of assessment** (*dd MMM yyyy*)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered '1 Feb 2021' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 01 Feb 2021 14:26:24 |



**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:07 |
| User entered '08:07'      | Emily Carney (b) (4)<br>(b) (4)  | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered '1 Feb 2021 08:07' | System           | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Temperature \(xxx.x\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:07 |
| User entered '96.9' F     | Emily Carney (b) (4)<br>(b) (4)  | 01 Feb 2021 14:26:24 |

US3802168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Route of measurement](#)

| Audit                        | User                                       | Time (GMT)           |
|------------------------------|--|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                           | 28 Apr 2021 21:40:14 |
| User signature succeeded.    | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'Other (Other)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:29**

[If Other, specify](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'Infrared'   | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Pulse \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:07 |
| User entered '70'         | Emily Carney (b) (4)<br>(b) (4)  | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered 'bpm' | System           | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:07 |
| User entered '20'         | Emily Carney (b) (4)<br>(b) (4)  | 01 Feb 2021 14:26:24 |



**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered 'breaths/min' | System           | 01 Feb 2021 14:26:24 |

US3802168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:29

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:07 |
| User entered '125'        | Emily Carney (b) (4)<br>(b) (4)  | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered 'mmHg' | System           | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:07 |
| User entered '85'         | Emily Carney (b) (4)<br>(b) (4)  | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered 'mmHg' | System           | 01 Feb 2021 14:26:24 |

US3802168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Timepoint](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                | 28 Apr 2021 21:40:14 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Emily Carney (b) (4)<br>(b) (4) | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Were vital signs assessed?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)           | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 01 Feb 2021 14:26:24 |

US3802168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)           | 01 Feb 2021 16:26:07 |
| User entered '1 Feb 2021' | (b) (4)<br>Emily Carney (b) (4) | 01 Feb 2021 14:26:24 |



**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:29**

**Time of assessment (00:00-23:59)**

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered '08:59'      | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered '1 Feb 2021 08:59' | System           | 01 Feb 2021 14:26:24 |

US3802168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

Temperature (xxx.x)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:07 |
| User entered '97.5' F     | Emily Carney (b) (4)<br>(b) (4)  | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Route of measurement](#)

| Audit                        | User                                       | Time (GMT)           |
|------------------------------|--|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                           | 28 Apr 2021 21:40:14 |
| User signature succeeded.    | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'Other (Other)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:29**

[If Other, specify](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered 'Infrared'   | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Pulse \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:07 |
| User entered '55'         | Emily Carney (b) (4)<br>(b) (4)  | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered 'bpm' | System           | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:07 |
| User entered '16'         | Emily Carney (b) (4)<br>(b) (4)  | 01 Feb 2021 14:26:24 |



US3802168

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:29

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered 'breaths/min' | System           | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:07 |
| User entered '123'        | Emily Carney (b) (4)<br>(b) (4)  | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered 'mmHg' | System           | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:07 |
| User entered '73'         | Emily Carney (b) (4)<br>(b) (4)  | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered 'mmHg' | System           | 01 Feb 2021 14:26:24 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:58:29**

[Was the physical examination performed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:07 |
| User entered 'No (N)'     | Emily Carney (b) (4)<br>(b) (4)  | 01 Feb 2021 14:26:30 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:58:29**

**Date of examination (dd MMM yyyy)**

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)                      | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 01 Feb 2021 14:26:30 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:58:29**

[Was study treatment given?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)           | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 01 Feb 2021 14:26:46 |



**US3802168**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:58:29**

[If No, reason not given](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:07 |
| User entered empty.       | Emily Carney (b) (4)<br>(b) (4)  | 01 Feb 2021 14:26:46 |

US3802168

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)           | 01 Feb 2021 16:26:07 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 01 Feb 2021 14:26:46 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:58:29**

[What was the study treatment? \(Unblinded\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered 'mRNA-1273'  | System           | 01 Feb 2021 14:26:46 |
| DataPoint set to visible. | System           | 12 Jan 2021 16:05:35 |

US3802168

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

What was the treatment date? (dd MMM yyyy)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)           | 01 Feb 2021 16:26:07 |
| User entered '1 Feb 2021' | (b) (4)<br>Emily Carney (b) (4) | 01 Feb 2021 14:26:46 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:58:29**

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:07 |
| User entered '08:29'      | Emily Carney (b) (4)<br>(b) (4)  | 01 Feb 2021 14:26:46 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:58:29**

[Treatment Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered '1 Feb 2021 08:29' | System           | 01 Feb 2021 14:26:46 |

US3802168

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

[Which arm was used to give treatment?](#)

| Audit                              | User                             | Time (GMT)           |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)                 | 28 Apr 2021 21:40:14 |
| User signature succeeded.          | Judith Martin (b) (4)<br>(b) (4) | 01 Feb 2021 16:26:07 |
| User entered 'Left Arm (LEFT ARM)' | Emily Carney (b) (4)<br>(b) (4)  | 01 Feb 2021 14:26:46 |

US3802168

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:29

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered 'ONCE' | System           | 01 Feb 2021 14:26:46 |



**US3802168**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:58:29**

[What was the route of administration for the study treatment?](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered 'INTRAMUSCULAR' | System           | 01 Feb 2021 14:26:46 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 21:40:14 |
| User signature succeeded. | Judith Martin (b) (4)           | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 01 Feb 2021 14:26:53 |

**US3802168**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:40:14 |
| User entered 'I'  | System           | 01 Feb 2021 14:26:53 |

**US3802168**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Was Contact Attempted?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 30 Apr 2021 22:26:00 |
| User signature succeeded. | Judith Martin (b) (4)                      | 13 Feb 2021 12:34:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Feb 2021 13:59:25 |

**US3802168**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

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

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 30 Apr 2021 22:26:00 |
| User signature succeeded. | Judith Martin (b) (4)                      | 13 Feb 2021 12:34:03 |
| User entered '9 Feb 2021' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Feb 2021 13:59:25 |

**US3802168**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                           | 30 Apr 2021 22:26:00 |
| User signature succeeded.                  | Judith Martin (b) (4)                      | 13 Feb 2021 12:34:03 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Feb 2021 13:59:25 |

**US3802168**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 30 Apr 2021 22:26:00 |
| User signature succeeded. | Judith Martin (b) (4)                      | 13 Feb 2021 12:34:03 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Feb 2021 13:59:25 |

US3802168

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:29

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 30 Apr 2021 22:26:00 |
| User signature succeeded. | Judith Martin (b) (4)                      | 13 Feb 2021 12:34:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 09 Feb 2021 13:59:32 |



**US3802168**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:29**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 22:26:00 |
| User entered 'I'  | System           | 09 Feb 2021 13:59:32 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Was this visit performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 13:59:00 |
| User signature succeeded. | Judith Martin (b) (4) | 03 Mar 2021 16:35:06 |
| User entered 'Yes (Y)'    | Lisa Vavro (b) (4)    | 01 Mar 2021 16:32:27 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 30 Apr 2021 13:59:00 |
| User signature succeeded. | Judith Martin (b) (4)                    | 03 Mar 2021 16:35:06 |
| User entered '1 Mar 2021' | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 01 Mar 2021 16:32:27 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                                     | Time (GMT)           |
|--------------------------------|--|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                         | 30 Apr 2021 13:59:00 |
| User signature succeeded.      | Judith Martin (b) (4)                    | 03 Mar 2021 16:35:06 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Lisa Vavro (b) (4)<br>(b) (4) | 01 Mar 2021 16:32:27 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:29**

[Folder OID](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 30 Apr 2021 13:59:00 |
| User entered 'OLD57' | System           | 01 Mar 2021 16:32:27 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Were vital signs assessed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 13:59:00 |
| User signature succeeded. | Judith Martin (b) (4) | 03 Mar 2021 16:35:06 |
| User entered 'Yes (Y)'    | Lisa Vavro (b) (4)    | 01 Mar 2021 16:34:08 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

**Date of assessment** (*dd MMM yyyy*)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 13:59:00 |
| User signature succeeded. | Judith Martin (b) (4) | 03 Mar 2021 16:35:06 |
| User entered '1 Mar 2021' | Lisa Vavro (b) (4)    | 01 Mar 2021 16:34:08 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 13:59:00 |
| User signature succeeded. | Judith Martin (b) (4) | 03 Mar 2021 16:35:06 |
| User entered '11:04'      | Lisa Vavro (b) (4)    | 01 Mar 2021 16:34:08 |



**US3802168**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 30 Apr 2021 13:59:00 |
| User entered '1 Mar 2021 11:04' | System           | 01 Mar 2021 16:34:08 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Temperature \(xxx.x\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 13:59:00 |
| User signature succeeded. | Judith Martin (b) (4) | 03 Mar 2021 16:35:06 |
| User entered '97.4' F     | Lisa Vavro (b) (4)    | 01 Mar 2021 16:34:08 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Route of measurement](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)      | 30 Apr 2021 13:59:00 |
| User signature succeeded.    | Judith Martin (b) (4) | 03 Mar 2021 16:35:06 |
| User entered 'Other (Other)' | Lisa Vavro (b) (4)    | 01 Mar 2021 16:34:08 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[If Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 13:59:00 |
| User signature succeeded. | Judith Martin (b) (4) | 03 Mar 2021 16:35:06 |
| User entered 'Infrared'   | Lisa Vavro (b) (4)    | 01 Mar 2021 16:34:08 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Pulse \(xxx\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 13:59:00 |
| User signature succeeded. | Judith Martin (b) (4) | 03 Mar 2021 16:35:06 |
| User entered '74'         | Lisa Vavro (b) (4)    | 01 Mar 2021 16:34:08 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 30 Apr 2021 13:59:00 |
| User entered 'bpm' | System           | 01 Mar 2021 16:34:08 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 13:59:00 |
| User signature succeeded. | Judith Martin (b) (4) | 03 Mar 2021 16:35:06 |
| User entered '18'         | Lisa Vavro (b) (4)    | 01 Mar 2021 16:34:08 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 30 Apr 2021 13:59:00 |
| User entered 'breaths/min' | System           | 01 Mar 2021 16:34:08 |



**US3802168**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 13:59:00 |
| User signature succeeded. | Judith Martin (b) (4) | 03 Mar 2021 16:35:06 |
| User entered '128'        | Lisa Vavro (b) (4)    | 01 Mar 2021 16:34:08 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 13:59:00 |
| User entered 'mmHg' | System           | 01 Mar 2021 16:34:08 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 13:59:00 |
| User signature succeeded. | Judith Martin (b) (4) | 03 Mar 2021 16:35:06 |
| User entered '84'         | Lisa Vavro (b) (4)    | 01 Mar 2021 16:34:08 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 13:59:00 |
| User entered 'mmHg' | System           | 01 Mar 2021 16:34:08 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 13:59:00 |
|                   |                  |                      |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:29**

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 13:59:00 |
|                   |                  |                      |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:58:29**

[Was the physical examination performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 13:59:00 |
| User signature succeeded. | Judith Martin (b) (4) | 03 Mar 2021 16:35:06 |
| User entered 'No (N)'     | (b) (4)               | 01 Mar 2021 16:34:14 |
|                           | Lisa Vavro (b) (4)    |                      |
|                           | (b) (4)               |                      |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:58:29**

**Date of examination (dd MMM yyyy)**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 13:59:00 |
| User signature succeeded. | Judith Martin (b) (4) | 03 Mar 2021 16:35:06 |
| User entered empty.       | Lisa Vavro (b) (4)    | 01 Mar 2021 16:34:14 |



**US3802168**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:58:29**

[Was the sample collected?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 30 Apr 2021 13:59:00 |
| User signature succeeded. | Judith Martin (b) (4)         | 03 Mar 2021 16:35:06 |
| User entered 'Yes (Y)'    | (b) (4)<br>Lisa Vavro (b) (4) | 01 Mar 2021 16:34:32 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:58:29**

**Collection date** (*dd MMM yyyy*)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 13:59:00 |
| User signature succeeded. | Judith Martin (b) (4) | 03 Mar 2021 16:35:06 |
| User entered '1 Mar 2021' | Lisa Vavro (b) (4)    | 01 Mar 2021 16:34:32 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:58:29**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 13:59:00 |
| User signature succeeded. | Judith Martin (b) (4) | 03 Mar 2021 16:35:06 |
| User entered '11:14'      | Lisa Vavro (b) (4)    | 01 Mar 2021 16:34:32 |

**US3802168**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:58:29**

[Collection date and time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 30 Apr 2021 13:59:00 |
| User entered '1 Mar 2021 11:14' | System           | 01 Mar 2021 16:34:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:58:29**

[Did the participant experience any adverse events?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 05:57:48 |
| User signature succeeded. | Judith Martin (b) (4) | 01 Feb 2021 16:26:07 |
| User entered 'Yes (Y)'    | Jennifer Nagg (b) (4) | 30 Sep 2020 19:39:11 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 13:35:06 |
|                   |                  |                      |

US3802168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:29

[Adverse event](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded.   | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Oral soft tissue conditions, HLT: Oral soft tissue signs and symptoms, PT: Paraesthesia oral, LLT: Paraesthesia oral - version MedDRA\23.0. | Coder Import (b) (4)  | 08 Oct 2020 05:31:30 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.  | Coder Import (b) (4)  | 08 Oct 2020 05:31:30 |
| Data point term sent to Coder   | System                | 30 Sep 2020 19:43:30 |
| User entered 'pins and needles feeling in mouth'  | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Was this a medically-attended AE?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered 'No (N)'     | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |



**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered 'No (N)'     | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

US3802168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4)            | 13 Feb 2021 12:34:03 |
| User entered 'No (N)'     | (b) (4)<br>Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded.  | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered '12 Sep 2020' | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered empty.       | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 13:35:06 |
| User entered empty. | System           | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Ongoing?](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 28 Apr 2021 13:35:06 |
| User signature succeeded.                                 | Judith Martin (b) (4)   | 13 Feb 2021 12:34:03 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4)                 |                      |
|   | Emily Dougherty (b) (4) | 15 Dec 2020 14:55:58 |
| User entered 'Yes (Y)'                                    | (b) (4)                 |                      |
|   | Jennifer Nagg (b) (4)   | 30 Sep 2020 19:42:32 |
|   | (b) (4)                 |                      |

US3802168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, end date (dd MMM yyyy)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 28 Apr 2021 13:35:06 |
| User signature succeeded.   | Judith Martin (b) (4)   | 13 Feb 2021 12:34:03 |
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).             | (b) (4)                 | 15 Dec 2020 14:56:08 |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System). | System                  | 15 Dec 2020 14:56:08 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).             | System                  | 15 Dec 2020 14:55:58 |
| User entered '04 Dec 2020' reason for change: Data Entry Error  | Emily Dougherty (b) (4) | 15 Dec 2020 14:55:58 |
| User entered empty.   | Jennifer Nagg (b) (4)   | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[End time \(00:00-23:59\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered empty.       | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |



**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 13:35:06 |
| User entered empty. | System           | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Severity](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded.                  | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Is the adverse event serious?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered 'No (N)'     | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Death](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered '0'          | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Life threatening](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered '0'          | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered '0'          | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered empty.       | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

**Hospital Discharge Date (dd MMM yyyy)**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered empty.       | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |



**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Admitted to ICU?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered empty.       | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Number of Days in ICU](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered empty.       | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered '0'          | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Congenital anomaly or birth defect](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered '0'          | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Other medically important event](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered '0'          | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Relationship to investigational product](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded.        | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered 'Related (RELATED)' | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

US3802168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:29

[Relationship to Study Procedure](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 28 Apr 2021 13:35:06 |
| User closed query 'Per CDM: Per sponsor review, as Relationship to IP is Related, please consider updating Relationship to Study Procedure as Not Related. ' (Site from DM).                              |                                  | 16 Feb 2021 08:10:35 |
| User signature succeeded.   | Judith Martin (b) (4)            | 13 Feb 2021 12:34:03 |
| Query 'Per CDM: Per sponsor review, as Relationship to IP is Related, please consider updating Relationship to Study Procedure as Not Related. ' answered with 'acknowledged and updated' (Site from DM). | (b) (4)<br>Jennifer Nagg (b) (4) | 12 Feb 2021 17:04:30 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error  | Jennifer Nagg (b) (4)            | 12 Feb 2021 17:04:12 |
| User opened query 'Per CDM: Per sponsor review, as Relationship to IP is Related, please consider updating Relationship to Study Procedure as Not Related. ' (Site from DM).                              | (b) (4), (b) (6)                 | 22 Dec 2020 17:40:52 |
| User entered 'Related (RELATED)'  | Jennifer Nagg (b) (4)            | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Action taken with investigational product](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded.  | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered 'None (NONE)' | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |



US3802168

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:29

None

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)   | 29 Apr 2021 12:18:38 |
|                            | (b) (4)                 |                      |
| Signature has been broken. | Emily Dougherty (b) (4) | 29 Apr 2021 12:12:17 |
|                            | (b) (4)                 |                      |
| Data hard locked.          | (b) (4), (b) (6)        | 28 Apr 2021 13:35:06 |
|                            |                         |                      |
| User signature succeeded.  | Judith Martin (b) (4)   | 19 Feb 2021 14:46:50 |
|                            | (b) (4)                 |                      |
| Signature has been broken. | Emily Carney (b) (4)    | 18 Feb 2021 20:58:28 |
|                            | (b) (4)                 |                      |
| User signature succeeded.  | Judith Martin (b) (4)   | 13 Feb 2021 12:34:03 |
|                            | (b) (4)                 |                      |
| User entered 'l'           | Jennifer Nagg (b) (4)   | 30 Sep 2020 19:42:32 |
|                            | (b) (4)                 |                      |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Concomitant Medication](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered '0'          | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Concomitant Procedure](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4) | 13 Feb 2021 12:34:03 |
| User entered '0'          | Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Outcome](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 28 Apr 2021 13:35:06 |
| User signature succeeded.   | Judith Martin (b) (4)   | 13 Feb 2021 12:34:03 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | (b) (4)                 |                      |
| Data Entry Error  | Emily Dougherty (b) (4) | 15 Dec 2020 14:56:08 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'    | (b) (4)                 |                      |
|   | Jennifer Nagg (b) (4)   | 30 Sep 2020 19:42:32 |
|   | (b) (4)                 |                      |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4)            | 13 Feb 2021 12:34:03 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Narrative](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 13:35:06 |
| User signature succeeded. | Judith Martin (b) (4)            | 13 Feb 2021 12:34:03 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 13:35:06 |
| User entered '0'  | System           | 30 Sep 2020 19:42:32 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 13:35:06 |
| User entered '0'  | System           | 30 Sep 2020 19:42:32 |



**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 13:35:06 |
|                   |                  |                      |

US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

[AEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Un-reviewed for Safety.                               | (b) (4), (b) (6)            | 29 Apr 2021 15:19:56 |
| Reviewed for Safety.                                  |                             | 29 Apr 2021 15:19:40 |
| Un-reviewed for Safety.                               |                             | 29 Apr 2021 14:59:02 |
| User signature succeeded.                             | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:17:56 |
| User entered<br>'USA-US098-2021-mRNA-1273-P301000004' |                             | 20 Apr 2021 18:17:35 |

US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

[Adverse event](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Haematopoietic neoplasms (excl leukaemias and lymphomas), HLT: Lymphoproliferative disorders NEC (excl leukaemias and lymphomas), PT: Castleman's disease, LLT: Castleman's disease - version MedDRA\23.0.   | Coder Import (b) (4)<br>(b) (4)     | 29 Apr 2021 22:21:17 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.  | Coder Import (b) (4)<br>(b) (4)     | 29 Apr 2021 22:21:17 |
| User closed query 'PV Query: Please consider updating the event terms to the underlying cause/etiology of the events.' (Site from Safety).  | (b) (4), (b) (6)                    | 29 Apr 2021 14:58:02 |
| User signature succeeded.   | Judith Martin (b) (4)<br>(b) (4)    | 29 Apr 2021 12:18:38 |
| Data point term sent to Coder   | System                              | 28 Apr 2021 14:12:02 |
| Query 'PV Query: Please consider updating the event terms to the underlying cause/etiology of the events.' answered with 'Participant has had this mass since 2008 with no change in condition. Participant electively chose to have it removed. The biopsy showed castleman's disease. How can a pre-existing condition be an AE when it has not worsened? Please advise.' (Site from Safety). | Melissa Andrasko (b) (4)<br>(b) (4) | 28 Apr 2021 14:11:48 |
| Coding entries removed.   | Melissa Andrasko (b) (4)<br>(b) (4) | 28 Apr 2021 14:11:18 |
| Signature has been broken.  | Melissa Andrasko (b) (4)<br>(b) (4) | 28 Apr 2021 14:11:18 |
| User entered 'EXCISION OF PERIHEPATIC MASS, Castleman's disease' reason for change: Data Entry Error  | Melissa Andrasko (b) (4)<br>(b) (4) | 28 Apr 2021 14:11:18 |
| User opened query 'PV Query: Please consider updating the event terms to the underlying cause/etiology of the events.' (Site from Safety).  | (b) (4), (b) (6)                    | 28 Apr 2021 12:34:16 |
| User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatic and hepatobiliary disorders NEC, PT: Hepatic mass, LLT: Hepatic mass - version MedDRA\23.0.  | Coder Import (b) (4)<br>(b) (4)     | 21 Apr 2021 12:30:01 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.  | Coder Import (b) (4)<br>(b) (4)     | 21 Apr 2021 12:30:01 |

US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

[Adverse event](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Mass excision, LLT: Mass excision - version MedDRA\\23.0. | Coder Import (b) (4)     | 21 Apr 2021 12:21:11 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4)     | 21 Apr 2021 12:21:11 |
| User signature succeeded.   | Judith Martin (b) (4)    | 19 Apr 2021 17:42:13 |
| Data point term sent to Coder   | System (b) (4)           | 19 Apr 2021 13:56:13 |
| User entered 'excision of perihepatic mass'   | Melissa Andrasko (b) (4) | 19 Apr 2021 13:55:48 |
|   | (b) (4)                  |                      |

US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

[Was this a medically-attended AE?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered 'No (N)'     | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered 'No (N)'     | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered '30 Mar 2021' | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |



**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Start time \(00:00-23:59\)](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered empty.       | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:58:29**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Apr 2021 13:55:48 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)    | 19 Apr 2021 17:42:13 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Melissa Andrasko (b) (4) | 19 Apr 2021 13:55:48 |
|                           | (b) (4)                  |                      |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:58:29**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered '30 Mar 2021' | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:58:29**

[End time \(00:00-23:59\)](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered empty.       | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:58:29**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Apr 2021 13:55:48 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Severity](#)

| Audit  | User   | Time (GMT)           |
|--|--|----------------------|
| User signature succeeded.                      | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

[Is the adverse event serious?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |



US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

Death

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered '0'          | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

[Life threatening](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered '0'          | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered '1'          | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

Hospital Admission Date (*dd MMM yyyy*)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered '30 Mar 2021' | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

Hospital Discharge Date (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)    | 19 Apr 2021 17:42:13 |
|                            | (b) (4)                  |                      |
| User entered '03 Apr 2021' | Melissa Andrasko (b) (4) | 19 Apr 2021 13:55:48 |
|                            | (b) (4)                  |                      |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Admitted to ICU?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered 'No (N)'     | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

[Number of Days in ICU](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered empty.       | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Persistent or significant disability or incapacity](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered '0'          | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |



US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

[Congenital anomaly or birth defect](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered '0'          | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

[Other medically important event](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered '0'          | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Relationship to investigational product](#)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                | Judith Martin (b) (4)    | 19 Apr 2021 17:42:13 |
|  | (b) (4)                  |                      |
| User entered 'Not Related (NOT RELATED)' | Melissa Andrasko (b) (4) | 19 Apr 2021 13:55:48 |
|  | (b) (4)                  |                      |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Relationship to Study Procedure](#)

| Audit                                    | User   | Time (GMT)           |
|--|--|----------------------|
| User signature succeeded.                | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Action taken with investigational product](#)

| Audit  | User   | Time (GMT)           |
|--|--|----------------------|
| User signature succeeded.                      | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

None

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered '0'          | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

[Concomitant Medication](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)    | 19 Apr 2021 17:42:13 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Melissa Andrasko (b) (4) | 19 Apr 2021 13:55:48 |
|                           | (b) (4)                  |                      |

US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

[Concomitant Procedure](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered '1'          | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |



**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Outcome](#)

| Audit  | User   | Time (GMT)           |
|--|--|----------------------|
| User signature succeeded.                              | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

US3802168

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 19 Apr 2021 17:42:13 |
| User entered empty.       | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 19 Apr 2021 13:55:48 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Narrative](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| User signature succeeded.   | Judith Martin (b) (4)               | 19 Apr 2021 17:42:13 |
| User entered 'Pathology showed Castleman's disease. No treatment needed just followup.' | (b) (4)<br>Melissa Andrasko (b) (4) | 19 Apr 2021 13:55:48 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 19 Apr 2021 13:55:48 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 19 Apr 2021 13:55:48 |

**US3802168**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 19 Apr 2021 13:55:48 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:58:29

Were any prior/concomitant medications and/or vaccinations taken?

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 03 May 2021 05:57:48 |
| User closed query 'Per CDM: As per Diary Dose 2 (1), Temperature day Log Lines 4 and 5 ediary reports, medication was taken for pain or fever. However, there is no corresponding medication recorded in the Concomitant Medications page. Please verify and update the details of the medication taken as appropriate.<br>' (Site from DM).   |                                  | 21 Dec 2020 09:06:22 |
| Query 'Per CDM: As per Diary Dose 2 (1), Temperature day Log Lines 4 and 5 ediary reports, medication was taken for pain or fever. However, there is no corresponding medication recorded in the Concomitant Medications page. Please verify and update the details of the medication taken as appropriate.<br>' answered with 'Participant was contacted at the Day 36 safety call, no medications are indicated in source document.' (Site from DM). | Lalicia Roman (b) (4)<br>(b) (4) | 18 Dec 2020 20:46:30 |
| User opened query 'Per CDM: As per Diary Dose 2 (1), Temperature day Log Lines 4 and 5 ediary reports, medication was taken for pain or fever. However, there is no corresponding medication recorded in the Concomitant Medications page. Please verify and update the details of the medication taken as appropriate.<br>' (Site from DM).   | (b) (4), (b) (6)                 | 10 Dec 2020 12:09:34 |
| User closed query 'Per CDM: As per Diary Dose 2 (1), Temperature day Log Lines 4 and 5 ediary reports, medication was taken for pain or fever. However, there is no corresponding medication recorded in the Concomitant Medications page. Please verify and update the details of the medication taken as appropriate.' (Site from DM).   | (b) (4), (b) (6)                 | 10 Dec 2020 12:09:18 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:58:29

Were any prior/concomitant medications and/or vaccinations taken?

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Query 'Per CDM: As per Diary Dose 2 (1), Temperature day Log Lines 4 and 5 diary reports, medication was taken for pain or fever. However, there is no corresponding medication recorded in the Concomitant Medications page. Please verify and update the details of the medication taken as appropriate.' answered with 'The participant was contacted at Safety call 36 but did not report taking any medication for pain and/or fever.' (Site from DM). | Lalicia Roman (b) (4)<br>(b) (4) | 03 Dec 2020 19:52:06 |
| User opened query 'Per CDM: As per Diary Dose 2 (1), Temperature day Log Lines 4 and 5 diary reports, medication was taken for pain or fever. However, there is no corresponding medication recorded in the Concomitant Medications page. Please verify and update the details of the medication taken as appropriate.' (Site from DM).   | (b) (4), (b) (6)                 | 19 Nov 2020 14:57:38 |
| User signature succeeded.   | Judith Martin (b) (4)<br>(b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'  | Emily Carney (b) (4)<br>(b) (4)  | 08 Sep 2020 15:15:57 |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:29

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 08 Sep 2020 15:18:43 |
| 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) | 08 Sep 2020 15:18:43 |
| Data point term sent to Coder   | System                          | 08 Sep 2020 15:18:13 |
| User entered 'Multivitamin'   | Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:17:50 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:29

[Prophylaxis](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' (Site from DM).              | (b) (4)<br>(b) (4), (b) (6)      | 18 Nov 2020 13:36:35 |
| Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' answered with 'Updated ' (Site from DM). | Emily Carney (b) (4)<br>(b) (4)  | 11 Nov 2020 16:19:17 |
| Signature has been broken.   | Emily Carney (b) (4)<br>(b) (4)  | 11 Nov 2020 16:19:05 |
| User entered 'Yes (Y)' reason for change: Data Entry Error   | Emily Carney (b) (4)<br>(b) (4)  | 11 Nov 2020 16:19:05 |
| User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' (Site from DM).              | (b) (4), (b) (6)                 | 10 Nov 2020 02:10:04 |
| User signature succeeded.  | Judith Martin (b) (4)<br>(b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'  | Emily Carney (b) (4)<br>(b) (4)  | 08 Sep 2020 15:17:50 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Indication](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Supplement' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:17:50 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:29

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'Unknown'    | Emily Carney (b) (4)  | 08 Sep 2020 15:17:50 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:29

[Dose unit](#)

| Audit                        | User                            | Time (GMT)           |
|------------------------------|---------------------------------|----------------------|
| User signature succeeded.    | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Other (OTHER)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:17:50 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:58:29**

If dose unit is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'Unknown'    | Emily Carney (b) (4)  | 08 Sep 2020 15:17:50 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:29

[Frequency](#)

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded.      | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'once daily (QD)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:17:50 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:58:29**

[If frequency is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:17:50 |
|                           | (b) (4)               |                      |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:29

[Route of administration](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'Oral (ORAL)' | Emily Carney (b) (4)  | 08 Sep 2020 15:17:50 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:58:29**

If route of administration is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:17:50 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2015' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:17:50 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:29

[Start date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:17:50 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Ongoing?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:17:50 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:17:50 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Was this medication taken for solicited event?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Emily Carney (b) (4)  | 08 Sep 2020 15:17:50 |
|                           | (b) (4)               |                      |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Sep 2020 15:17:50 |



**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Sep 2020 15:17:50 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 08 Sep 2020 15:17:50 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:29

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: VITAMIN E NOS, PRODUCTSYNONYM: VITAMIN E [VITAMIN E NOS] - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 08 Sep 2020 15:19:48 |
| 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) | 08 Sep 2020 15:19:48 |
| Data point term sent to Coder  | System                          | 08 Sep 2020 15:19:16 |
| User entered 'Vitamin E'   | Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:18:23 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:29

[Prophylaxis](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User signature succeeded.   | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.<br>' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6)      | 10 Nov 2020 02:15:37 |
| Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.<br>' answered with 'Updated' (Site from DM). | Emily Carney (b) (4)<br>(b) (4)  | 09 Nov 2020 18:37:59 |
| Signature has been broken.  | Emily Carney (b) (4)<br>(b) (4)  | 09 Nov 2020 18:37:53 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | Emily Carney (b) (4)<br>(b) (4)  | 09 Nov 2020 18:37:53 |
| User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.<br>' (Site from DM).             | (b) (4), (b) (6)                 | 04 Nov 2020 02:38:22 |
| User signature succeeded.   | Judith Martin (b) (4)<br>(b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'   | Emily Carney (b) (4)<br>(b) (4)  | 08 Sep 2020 15:18:23 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Indication](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Supplement' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:18:23 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:29

[Dose per administration](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '400'        | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:18:23 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Dose unit](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'IU (IU)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:18:23 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:58:29**

If dose unit is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:18:23 |
|                           | (b) (4)                         |                      |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:29

[Frequency](#)

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded.      | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'once daily (QD)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:18:23 |
|                                | (b) (4)                         |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:29

If frequency is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:18:23 |
|                           | (b) (4)                         |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:29

[Route of administration](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Oral (ORAL)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:18:23 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:29

If route of administration is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:18:23 |
|                           | (b) (4)                         |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2020' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:18:23 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:29

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered '0'          | Emily Carney (b) (4)  | 08 Sep 2020 15:18:23 |
|                           | (b) (4)               |                      |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 08 Sep 2020 15:18:23 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:18:23 |
|                           | (b) (4)               |                      |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:29

[Was this medication taken for solicited event?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:18:23 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Sep 2020 15:18:23 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Sep 2020 15:18:23 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 08 Sep 2020 15:18:23 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:29

Name of Medication

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User coded data point as ATC:<br>DERMATOLOGICALS, ATC: EMOLLIENTS<br>AND PROTECTIVES, ATC: EMOLLIENTS AND<br>PROTECTIVES, ATC: OTHER EMOLLIENTS<br>AND PROTECTIVES, PRODUCT: AMMONIUM<br>LACTATE - version<br>WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 08 Sep 2020 15:54:49 |
| 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)            | 08 Sep 2020 15:54:49 |
| Data point term sent to Coder  | System                                     | 08 Sep 2020 15:20:17 |
| User entered 'Ammonium lactate 12% topical cream'  | Emily Carney (b) (4)<br>(b) (4)            | 08 Sep 2020 15:19:16 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:29

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Emily Carney (b) (4)  | 08 Sep 2020 15:19:16 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:29

[Indication](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).                  | (b) (4), (b) (6)                 | 12 Nov 2020 06:57:19 |
| Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'Added to MH ' (Site from DM). | Emily Carney (b) (4)<br>(b) (4)  | 11 Nov 2020 16:20:29 |
| User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).                  | (b) (4), (b) (6)                 | 10 Nov 2020 01:57:46 |
| User signature succeeded.   | Judith Martin (b) (4)<br>(b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'Dry feet'   | Emily Carney (b) (4)<br>(b) (4)  | 08 Sep 2020 15:19:16 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'Unknown'    | Emily Carney (b) (4)  | 08 Sep 2020 15:19:16 |
|                           | (b) (4)               |                      |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:29

[Dose unit](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| User signature succeeded.    | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'Other (OTHER)' | Emily Carney (b) (4)  | 08 Sep 2020 15:19:16 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:58:29**

If dose unit is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'Unknown'    | Emily Carney (b) (4)  | 08 Sep 2020 15:19:16 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:29

[Frequency](#)

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded.      | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'as needed (PRN)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:19:16 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:58:29**

[If frequency is Other, specify](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:19:16 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:29

[Route of administration](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| User signature succeeded.        | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'Topical (TOPICAL)' | Emily Carney (b) (4)  | 08 Sep 2020 15:19:16 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:58:29**

If route of administration is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:19:16 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2016' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:19:16 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:29

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered '0'          | Emily Carney (b) (4)  | 08 Sep 2020 15:19:16 |
|                           | (b) (4)               |                      |



**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 08 Sep 2020 15:19:16 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:19:16 |
|                           | (b) (4)               |                      |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Was this medication taken for solicited event?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Emily Carney (b) (4)  | 08 Sep 2020 15:19:16 |
|                           | (b) (4)               |                      |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Sep 2020 15:19:16 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Sep 2020 15:19:16 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Sep 2020 15:19:16 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:29

Name of Medication

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User closed query 'Per MM, please review and confirm as this medication meet EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids $\geq$ 20 mg/day of prednisone equivalent)' and Please raise a PD accordingly. ' (Site from DM).  | (b) (4), (b) (6)                 | 28 Oct 2020 12:20:58 |
| Query 'Per MM, please review and confirm as this medication meet EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids $\geq$ 20 mg/day of prednisone equivalent)' and Please raise a PD accordingly. ' answered with 'This is not a systemic immunosuppressant drug.' (Site from DM). | Lalicia Roman (b) (4)<br>(b) (4) | 22 Oct 2020 19:25:08 |
| User opened query 'Per MM, please review and confirm as this medication meet EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids $\geq$ 20 mg/day of prednisone equivalent)' and Please raise a PD accordingly. ' (Site from DM).  | (b) (4), (b) (6)                 | 08 Oct 2020 08:24:15 |
| User signature succeeded.  | Judith Martin (b) (4)<br>(b) (4) | 14 Sep 2020 16:30:52 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ANTIINFLAMMATORY AGENTS, ATC: AMINOSALICYLIC ACID AND SIMILAR AGENTS, PRODUCT: MESALAZINE, PRODUCTSYNONYM: MESALAMINE - version WHODrug-Global-B3\202003.  | Coder Import (b) (4)<br>(b) (4)  | 08 Sep 2020 16:10:43 |
| 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)  | 08 Sep 2020 16:10:43 |
| Data point term sent to Coder  | System                           | 08 Sep 2020 15:20:17 |
| User entered 'Mesalamine/Enema'  | Emily Carney (b) (4)<br>(b) (4)  | 08 Sep 2020 15:20:15 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:29

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Emily Carney (b) (4)  | 08 Sep 2020 15:20:15 |
|                           | (b) (4)               |                      |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:29

[Indication](#)

| Audit                             | User                            | Time (GMT)           |
|-----------------------------------|---------------------------------|----------------------|
| User signature succeeded.         | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Ulcerative colitis' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:20:15 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:29

[Dose per administration](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '4/60'       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:20:15 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Dose unit](#)

| Audit                        | User                            | Time (GMT)           |
|------------------------------|---------------------------------|----------------------|
| User signature succeeded.    | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Other (OTHER)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:20:15 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:58:29**

If dose unit is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'g/mL'       | Emily Carney (b) (4)  | 08 Sep 2020 15:20:15 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:29

[Frequency](#)

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded.      | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'as needed (PRN)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:20:15 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:58:29**

[If frequency is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:20:15 |
|                           | (b) (4)               |                      |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Route of administration](#)

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded.      | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Rectal (RECTAL)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:20:15 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:58:29**

If route of administration is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:20:15 |
|                           | (b) (4)               |                      |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2015' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:20:15 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:29

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered '0'          | Emily Carney (b) (4)  | 08 Sep 2020 15:20:15 |
|                           | (b) (4)               |                      |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 08 Sep 2020 15:20:15 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:20:15 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:29

[Was this medication taken for solicited event?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Emily Carney (b) (4)  | 08 Sep 2020 15:20:15 |
|                           | (b) (4)               |                      |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Sep 2020 15:20:15 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Sep 2020 15:20:15 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Sep 2020 15:20:15 |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:29

[Name of Medication](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| 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)  | 08 Sep 2020 15:22:49 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)  | 08 Sep 2020 15:22:49 |
| Data point term sent to Coder  | System                | 08 Sep 2020 15:21:18 |
| User entered 'Zyrtec'  | Emily Carney (b) (4)  | 08 Sep 2020 15:20:43 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:29

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Emily Carney (b) (4)  | 08 Sep 2020 15:20:43 |
|                           | (b) (4)               |                      |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Indication](#)

| Audit                             | User                                       | Time (GMT)           |
|-----------------------------------|--|----------------------|
| User signature succeeded.         | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Seasonal allergies' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:20:43 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:29

[Dose per administration](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '10'         | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:20:43 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:29

[Dose unit](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'mg (mg)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:20:43 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:58:29**

If dose unit is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:20:43 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:29

[Frequency](#)

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded.      | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'once daily (QD)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:20:43 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:29

If frequency is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:20:43 |



**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Route of administration](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'Oral (ORAL)' | Emily Carney (b) (4)  | 08 Sep 2020 15:20:43 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:58:29**

If route of administration is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:20:43 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2004' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:20:43 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:20:43 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Ongoing?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:20:43 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:20:43 |
|                           | (b) (4)               |                      |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Was this medication taken for solicited event?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:20:43 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Sep 2020 15:20:43 |



**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Sep 2020 15:20:43 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 08 Sep 2020 15:20:43 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:29

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 08 Sep 2020 16:02:54 |
| 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) | 08 Sep 2020 16:02:54 |
| Data point term sent to Coder  | System                          | 08 Sep 2020 15:22:18 |
| User entered 'Fluticasone propionate 50mcg/ actuation nasal spray'   | Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:21:48 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:29

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Emily Carney (b) (4)  | 08 Sep 2020 15:21:48 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:29

[Indication](#)

| Audit                             | User                                       | Time (GMT)           |
|-----------------------------------|--|----------------------|
| User signature succeeded.         | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Seasonal allergies' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:21:48 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:29

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered '2'          | Emily Carney (b) (4)  | 08 Sep 2020 15:21:48 |
|                           | (b) (4)               |                      |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Dose unit](#)

| Audit                        | User                                       | Time (GMT)           |
|------------------------------|--|----------------------|
| User signature succeeded.    | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Other (OTHER)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:21:48 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:29

If dose unit is Other, specify

| Audit                           | User                            | Time (GMT)           |
|---------------------------------|---------------------------------|----------------------|
| User signature succeeded.       | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Sprays / nostril' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:21:48 |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:29

[Frequency](#)

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded.      | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'once daily (QD)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:21:48 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:29

[If frequency is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:21:48 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:29

[Route of administration](#)

| Audit                        | User                            | Time (GMT)           |
|------------------------------|---------------------------------|----------------------|
| User signature succeeded.    | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Nasal (NASAL)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:21:48 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:29

If route of administration is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:21:48 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2004' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:21:48 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:21:48 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 08 Sep 2020 15:21:48 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:21:48 |



US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Was this medication taken for solicited event?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:21:48 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Sep 2020 15:21:48 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Sep 2020 15:21:48 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 08 Sep 2020 15:21:48 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:29

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS, PRODUCT: AZELASTINE - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 08 Sep 2020 15:58:50 |
| 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) | 08 Sep 2020 15:58:50 |
| Data point term sent to Coder   | System                          | 08 Sep 2020 15:23:22 |
| User entered 'Azelastine 137 mcg nasal spray'   | Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:23:01 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:29

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Emily Carney (b) (4)  | 08 Sep 2020 15:23:01 |
|                           | (b) (4)               |                      |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:58:29**

[Indication](#)

| Audit                             | User                                       | Time (GMT)           |
|-----------------------------------|--|----------------------|
| User signature succeeded.         | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Seasonal allergies' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:23:01 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:29

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered '2'          | Emily Carney (b) (4)  | 08 Sep 2020 15:23:01 |
|                           | (b) (4)               |                      |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:29

[Dose unit](#)

| Audit                        | User                            | Time (GMT)           |
|------------------------------|---------------------------------|----------------------|
| User signature succeeded.    | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Other (OTHER)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:23:01 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:58:29**

[If dose unit is Other, specify](#)

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded.      | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Spray / nostril' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:23:01 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:29

[Frequency](#)

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded.      | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'as needed (PRN)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:23:01 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:58:29**

[If frequency is Other, specify](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:23:01 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:58:29**

[Route of administration](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| User signature succeeded.    | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'Nasal (NASAL)' | Emily Carney (b) (4)  | 08 Sep 2020 15:23:01 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:58:29**

If route of administration is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:23:01 |
|                           | (b) (4)                         |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2020' | Emily Carney (b) (4)  | 08 Sep 2020 15:23:01 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:29

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered '0'          | Emily Carney (b) (4)  | 08 Sep 2020 15:23:01 |
|                           | (b) (4)               |                      |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:29

[Ongoing?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:23:01 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:23:01 |
|                           | (b) (4)                         |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:29

[Was this medication taken for solicited event?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:23:01 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:58:29**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Sep 2020 15:23:01 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Sep 2020 15:23:01 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Sep 2020 15:23:01 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:29

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: BUDESONIDE - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 08 Sep 2020 15:55:45 |
| 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) | 08 Sep 2020 15:55:45 |
| Data point term sent to Coder  | System                          | 08 Sep 2020 15:24:24 |
| User entered 'Budesonide nasal irrigation'   | Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:23:54 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:29

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Emily Carney (b) (4)  | 08 Sep 2020 15:23:54 |
|                           | (b) (4)               |                      |



**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:58:29**

[Indication](#)

| Audit                            | User                                       | Time (GMT)           |
|----------------------------------|--|----------------------|
| User signature succeeded.        | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Chronic sinusitis' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:23:54 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:29

[Dose per administration](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '0.5'        | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:23:54 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:29

[Dose unit](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'mg (mg)'    | Emily Carney (b) (4)  | 08 Sep 2020 15:23:54 |
|                           | (b) (4)               |                      |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:58:29**

If dose unit is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:23:54 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:29

[Frequency](#)

| Audit                          | User                                       | Time (GMT)           |
|--------------------------------|--|----------------------|
| User signature succeeded.      | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'once daily (QD)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:23:54 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:29

[If frequency is Other, specify](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:23:54 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:29

[Route of administration](#)

| Audit                        | User                            | Time (GMT)           |
|------------------------------|---------------------------------|----------------------|
| User signature succeeded.    | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Nasal (NASAL)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:23:54 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:29

If route of administration is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:23:54 |
|                           | (b) (4)               |                      |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2020' | Emily Carney (b) (4)  | 08 Sep 2020 15:23:54 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:29

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered '0'          | Emily Carney (b) (4)  | 08 Sep 2020 15:23:54 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:29

[Ongoing?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:23:54 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:23:54 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:29

[Was this medication taken for solicited event?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Emily Carney (b) (4)  | 08 Sep 2020 15:23:54 |
|                           | (b) (4)               |                      |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:58:29**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Sep 2020 15:23:54 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Sep 2020 15:23:54 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 08 Sep 2020 15:23:54 |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:29

Name of Medication

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: SODIUM BICARBONATE;SODIUM CHLORIDE, PRODUCTSYNONYM: NASAFLO NETI POT [SODIUM BICARBONATE;SODIUM CHLORIDE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 16 Sep 2020 08:47:36 |
| 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 08:47:36 |
| User signature succeeded.  | Judith Martin (b) (4)<br>(b) (4) | 14 Sep 2020 16:30:52 |
| Data point term sent to Coder  | System                           | 08 Sep 2020 15:25:24 |
| User entered 'Sodium bicarbonate - sodium chloride - Neti Pot nasal rinse packet'  | Emily Carney (b) (4)<br>(b) (4)  | 08 Sep 2020 15:24:55 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:29

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Emily Carney (b) (4)  | 08 Sep 2020 15:24:55 |
|                           | (b) (4)               |                      |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:58:29**

[Indication](#)

| Audit                            | User                                       | Time (GMT)           |
|----------------------------------|--|----------------------|
| User signature succeeded.        | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'Chronic sinusitis' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:24:55 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:29

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered '1'          | Emily Carney (b) (4)  | 08 Sep 2020 15:24:55 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:29

[Dose unit](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| User signature succeeded.    | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'Other (OTHER)' | Emily Carney (b) (4)  | 08 Sep 2020 15:24:55 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:29

If dose unit is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'Packet'     | Emily Carney (b) (4)  | 08 Sep 2020 15:24:55 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:29

[Frequency](#)

| Audit                          | User                                       | Time (GMT)           |
|--------------------------------|--|----------------------|
| User signature succeeded.      | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User entered 'as needed (PRN)' | (b) (4)<br>Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:24:55 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:29

[If frequency is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:24:55 |
|                           | (b) (4)               |                      |



**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:58:29**

[Route of administration](#)

| Audit                        | User                            | Time (GMT)           |
|------------------------------|---------------------------------|----------------------|
| User signature succeeded.    | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Nasal (NASAL)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:24:55 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:58:29**

If route of administration is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:24:55 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2020' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:24:55 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:29

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered '0'          | Emily Carney (b) (4)  | 08 Sep 2020 15:24:55 |
|                           | (b) (4)               |                      |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:58:29**

[Ongoing?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:24:55 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:24:55 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:29

[Was this medication taken for solicited event?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Emily Carney (b) (4)  | 08 Sep 2020 15:24:55 |
|                           | (b) (4)               |                      |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:58:29**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Sep 2020 15:24:55 |



**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Sep 2020 15:24:55 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Sep 2020 15:24:55 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:29

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 08 Sep 2020 15:28:11 |
| 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) | 08 Sep 2020 15:28:11 |
| Data point term sent to Coder   | System                          | 08 Sep 2020 15:26:30 |
| User entered 'Vitamin D3'   | Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:25:29 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:29

[Prophylaxis](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User signature succeeded.   | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.<br>' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6)      | 10 Nov 2020 02:13:09 |
| Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.<br>' answered with 'Updated' (Site from DM). | Emily Carney (b) (4)<br>(b) (4)  | 09 Nov 2020 18:38:29 |
| Signature has been broken.  | Emily Carney (b) (4)<br>(b) (4)  | 09 Nov 2020 18:38:12 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | Emily Carney (b) (4)<br>(b) (4)  | 09 Nov 2020 18:38:12 |
| User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.<br>' (Site from DM).             | (b) (4), (b) (6)                 | 04 Nov 2020 02:25:37 |
| User signature succeeded.   | Judith Martin (b) (4)<br>(b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'   | Emily Carney (b) (4)<br>(b) (4)  | 08 Sep 2020 15:25:29 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:29

[Indication](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Supplement' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:25:29 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:29

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered '2000'       | Emily Carney (b) (4)  | 08 Sep 2020 15:25:29 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:29

[Dose unit](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'IU (IU)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:25:29 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:58:29**

[If dose unit is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:25:29 |
|                           | (b) (4)               |                      |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:29

[Frequency](#)

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded.      | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'once daily (QD)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:25:29 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:58:29**

[If frequency is Other, specify](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:25:29 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:29

[Route of administration](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'Oral (ORAL)' | Emily Carney (b) (4)  | 08 Sep 2020 15:25:29 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:58:29**

If route of administration is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:25:29 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2018' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:25:29 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:29

[Start date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered '0'          | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:25:29 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:58:29**

[Ongoing?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:25:29 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:25:29 |
|                           | (b) (4)                         |                      |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:29

[Was this medication taken for solicited event?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:25:29 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:58:29**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Sep 2020 15:25:29 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Sep 2020 15:25:29 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 08 Sep 2020 15:25:29 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:29

[Name of Medication](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)                      | 14 Sep 2020 16:30:52 |
| User coded data point as ATC:<br>DERMATOLOGICALS, ATC:<br>CORTICOSTEROIDS, DERMATOLOGICAL<br>PREPARATIONS, ATC: CORTICOSTEROIDS,<br>PLAIN, ATC: CORTICOSTEROIDS, VERY<br>POTENT (GROUP IV), PRODUCT:<br>CLOBETASOL PROPIONATE,<br>PRODUCTSYNONYM: CLOBETASOL 0.05% -<br>version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 08 Sep 2020 15:58:50 |
| 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)            | 08 Sep 2020 15:58:50 |
| Data point term sent to Coder  | System                                     | 08 Sep 2020 15:26:30 |
| User entered 'Clobetasol 0.05% topical ointment'   | Emily Carney (b) (4)<br>(b) (4)            | 08 Sep 2020 15:26:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:29

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Emily Carney (b) (4)  | 08 Sep 2020 15:26:25 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:29

[Indication](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Dry skin'   | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:26:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:29

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'Unknown'    | Emily Carney (b) (4)  | 08 Sep 2020 15:26:25 |
|                           | (b) (4)               |                      |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:29

[Dose unit](#)

| Audit                        | User                            | Time (GMT)           |
|------------------------------|---------------------------------|----------------------|
| User signature succeeded.    | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Other (OTHER)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:26:25 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:58:29**

If dose unit is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'Unknown'    | Emily Carney (b) (4)  | 08 Sep 2020 15:26:25 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:29

[Frequency](#)

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded.      | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'as needed (PRN)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:26:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:29

If frequency is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:26:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:29

[Route of administration](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| User signature succeeded.        | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'Topical (TOPICAL)' | Emily Carney (b) (4)  | 08 Sep 2020 15:26:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:29

If route of administration is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:26:25 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2020' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:26:25 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered '0'          | Emily Carney (b) (4)  | 08 Sep 2020 15:26:25 |
|                           | (b) (4)               |                      |



**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:58:29**

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 08 Sep 2020 15:26:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:26:25 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:29

[Was this medication taken for solicited event?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:26:25 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:58:29**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Sep 2020 15:26:25 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Sep 2020 15:26:25 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Sep 2020 15:26:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:29

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 08 Sep 2020 15:28:48 |
| 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) | 08 Sep 2020 15:28:48 |
| Data point term sent to Coder  | System                          | 08 Sep 2020 15:27:33 |
| User entered 'Zoloft'  | Emily Carney (b) (4)<br>(b) (4) | 08 Sep 2020 15:27:01 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:29

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Emily Carney (b) (4)  | 08 Sep 2020 15:27:01 |
|                           | (b) (4)               |                      |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:29

[Indication](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Anxiety'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:27:01 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:29

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered '50'         | Emily Carney (b) (4)  | 08 Sep 2020 15:27:01 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:29

[Dose unit](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'mg (mg)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:27:01 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:58:29**

If dose unit is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:27:01 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:29

[Frequency](#)

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded.      | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'once daily (QD)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:27:01 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:29

[If frequency is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:27:01 |
|                           | (b) (4)               |                      |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:58:29**

[Route of administration](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'Oral (ORAL)' | Emily Carney (b) (4)  | 08 Sep 2020 15:27:01 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:29

If route of administration is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:27:01 |
|                           | (b) (4)               |                      |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2015' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:27:01 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:29

Start date completely unknown

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered '0'          | Emily Carney (b) (4)  | 08 Sep 2020 15:27:01 |
|                           | (b) (4)               |                      |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:58:29**

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 08 Sep 2020 15:27:01 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:27:01 |
|                           | (b) (4)               |                      |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:58:29**

[Was this medication taken for solicited event?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:27:01 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:58:29**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Sep 2020 15:27:01 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Sep 2020 15:27:01 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 08 Sep 2020 15:27:01 |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:29

[Name of Medication](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User signature succeeded.   | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| 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 - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)  | 08 Sep 2020 16:01:50 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)  | 08 Sep 2020 16:01:50 |
| Data point term sent to Coder   | System                | 08 Sep 2020 15:28:34 |
| User entered 'Esomeprazole magnesium'   | Emily Carney (b) (4)  | 08 Sep 2020 15:27:41 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:29

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Emily Carney (b) (4)  | 08 Sep 2020 15:27:41 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:29

[Indication](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'Heart burn' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:27:41 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:29

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered '40'         | Emily Carney (b) (4)  | 08 Sep 2020 15:27:41 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:29

[Dose unit](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'mg (mg)'    | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:27:41 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:29

If dose unit is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:27:41 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:29

[Frequency](#)

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded.      | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'once daily (QD)' | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:27:41 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:58:29**

[If frequency is Other, specify](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered empty.       | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:27:41 |



US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:58:29**

[Route of administration](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'Oral (ORAL)' | Emily Carney (b) (4)  | 08 Sep 2020 15:27:41 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:58:29**

If route of administration is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:27:41 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User signature succeeded.   | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2010). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6)      | 18 Nov 2020 13:36:43 |
| Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2010). Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'Updated and now matches the corresponding MH ' (Site from DM). | Emily Carney (b) (4)<br>(b) (4)  | 11 Nov 2020 16:48:35 |
| Signature has been broken.  | Emily Carney (b) (4)<br>(b) (4)  | 11 Nov 2020 16:48:22 |
| User entered 'UN UNK 2010' reason for change: Data Entry Error  | Emily Carney (b) (4)<br>(b) (4)  | 11 Nov 2020 16:48:22 |
| User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2010). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).   | (b) (4), (b) (6)                 | 10 Nov 2020 02:07:11 |
| User signature succeeded.   | Judith Martin (b) (4)<br>(b) (4) | 14 Sep 2020 16:30:52 |
| User entered 'UN UNK 2004'  | Emily Carney (b) (4)<br>(b) (4)  | 08 Sep 2020 15:27:41 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:29

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered '0'          | Emily Carney (b) (4)  | 08 Sep 2020 15:27:41 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:29

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 08 Sep 2020 15:27:41 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 14 Sep 2020 16:30:52 |
|                           | (b) (4)               |                      |
| User entered empty.       | Emily Carney (b) (4)  | 08 Sep 2020 15:27:41 |
|                           | (b) (4)               |                      |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:58:29**

[Was this medication taken for solicited event?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)           | 14 Sep 2020 16:30:52 |
| User entered 'No (N)'     | (b) (4)<br>Emily Carney (b) (4) | 08 Sep 2020 15:27:41 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:58:29**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Sep 2020 15:27:41 |



**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Sep 2020 15:27:41 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 08 Sep 2020 15:27:41 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:29

[Name of Medication](#)

| Audit  | User                            | Time (GMT)                                   |
|--|---------------------------------|--|
| Data hard locked.  | (b) (4), (b) (6)                | 23 Apr 2021 09:15:47                         |
| User signature succeeded.  | Judith Martin (b) (4)           | 19 Feb 2021 14:46:50                         |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)            | 16 Sep 2020 14:38:47                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)            | 16 Sep 2020 14:38:47                         |
| Data point term sent to Coder User entered 'Tylenol'   | System<br>Lalicia Roman (b) (4) | 16 Sep 2020 14:37:52<br>16 Sep 2020 14:37:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:29

[Prophylaxis](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 23 Apr 2021 09:15:47 |
| User signature succeeded. | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User entered 'No (N)'     | (b) (4)<br>Lalicia Roman (b) (4) | 16 Sep 2020 14:37:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:29

[Indication](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 23 Apr 2021 09:15:47 |
| User closed query 'Per CDM Re-query: Site response indicates this medication was taken for symptoms reported in eDiary. However, in order to satisfy previous query, please confirm there is no criteria met for this indication to be reported as an Adverse Event. If necessary, please check with PI. Thank you.' (Site from DM). |                        | 23 Feb 2021 13:14:00 |
| User signature succeeded.  | Judith Martin (b) (4)  | 19 Feb 2021 14:46:50 |
| Query 'Per CDM Re-query: Site response indicates this medication was taken for symptoms reported in eDiary. However, in order to satisfy previous query, please confirm there is no criteria met for this indication to be reported as an Adverse Event. If necessary, please check with PI. Thank you.'                             | (b) (4)                |                      |
| answered with 'No criteria was met to report this as an AE.' (Site from DM).   | Emily Carney (b) (4)   | 18 Feb 2021 19:27:37 |
| User opened query 'Per CDM Re-query: Site response indicates this medication was taken for symptoms reported in eDiary. However, in order to satisfy previous query, please confirm there is no criteria met for this indication to be reported as an Adverse Event. If necessary, please check with PI. Thank you.' (Site from DM). | (b) (4)                |                      |
| User closed query 'Per DM CLR-RQ: Please confirm that there is no criteria met for this indication to be reported as an AE. If there is, record an AE as appropriate. Otherwise, provide confirmation or clarification.  | (b) (4), (b) (6)       | 25 Jan 2021 15:27:08 |
| ' (Site from DM).  |                        |                      |
| Query 'Per DM CLR-RQ: Please confirm that there is no criteria met for this indication to be reported as an AE. If there is, record an AE as appropriate. Otherwise, provide confirmation or clarification.  | Dominic Kramer (b) (4) | 22 Jan 2021 18:35:06 |
| ' answered with 'Med taken for symptoms previously reported in patient ed diary ' (Site from DM).  | (b) (4)                |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:29

[Indication](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User opened query 'Per DM CLR-RQ: Please confirm that there is no criteria met for this indication to be reported as an AE. If there is, record an AE as appropriate. Otherwise, provide confirmation or clarification.<br />' (Site from DM).  | (b) (4), (b) (6)      | 12 Jan 2021 06:21:58 |
| User closed query 'Per CDM: Please review pages 34-35 of CCGs v2.0 and section 8.3.4 of Protocol Amendment 4 and confirm if CM#14 indication meets AE reporting criteria. If yes, please update the eCRF accordingly. Thank you.  |                       | 14 Dec 2020 13:23:51 |
| ' (Site from DM).   |                       |                      |
| Query 'Per CDM: Please review pages 34-35 of CCGs v2.0 and section 8.3.4 of Protocol Amendment 4 and confirm if CM#14 indication meets AE reporting criteria. If yes, please update the eCRF accordingly. Thank you.  | Lalicia Roman (b) (4) | 03 Dec 2020 19:54:36 |
| ' answered with 'Participant reported having pain/fever in the diary however, they did not report taking the medication during their Day 36 safety call.'   | (b) (4)               |                      |
| (Site from DM).   |                       |                      |
| User opened query 'Per CDM: Please review pages 34-35 of CCGs v2.0 and section 8.3.4 of Protocol Amendment 4 and confirm if CM#14 indication meets AE reporting criteria. If yes, please update the eCRF accordingly. Thank you.  | (b) (4), (b) (6)      | 18 Nov 2020 13:36:58 |
| ' (Site from DM).   |                       |                      |
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEAD ACHE, MUSCLE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEAD ACHE, MUSCLE PAIN did not meet the AE reporting criteria.' (Site from DM). |                       | 18 Nov 2020 13:36:58 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:29

[Indication](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEAD ACHE, MUSCLE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEAD ACHE, MUSCLE PAIN did not meet the AE reporting criteria.' answered with 'There is no AE as it was reported in the diary. ' (Site from DM). | Emily Carney (b) (4)  | 11 Nov 2020 16:27:17 |
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEAD ACHE, MUSCLE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEAD ACHE, MUSCLE PAIN did not meet the AE reporting criteria.' (Site from DM).  | (b) (4), (b) (6)      | 10 Nov 2020 02:11:01 |
| User entered 'head ache, muscle pain'  | Lalicia Roman (b) (4) | 16 Sep 2020 14:37:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:29

[Dose per administration](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 23 Apr 2021 09:15:47 |
| User signature succeeded. | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User entered '500'        | (b) (4)<br>Lalicia Roman (b) (4) | 16 Sep 2020 14:37:25 |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:29

[Dose unit](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 23 Apr 2021 09:15:47 |
| User signature succeeded. | Judith Martin (b) (4)                       | 19 Feb 2021 14:46:50 |
| User entered 'mg (mg)'    | (b) (4)<br>Lalicia Roman (b) (4)<br>(b) (4) | 16 Sep 2020 14:37:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:29

If dose unit is Other, specify

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 23 Apr 2021 09:15:47 |
| User signature succeeded. | Judith Martin (b) (4)                       | 19 Feb 2021 14:46:50 |
| User entered empty.       | (b) (4)<br>Lalicia Roman (b) (4)<br>(b) (4) | 16 Sep 2020 14:37:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:29

[Frequency](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                 | 23 Apr 2021 09:15:47 |
| User signature succeeded.      | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User entered 'as needed (PRN)' | (b) (4)<br>Lalicia Roman (b) (4) | 16 Sep 2020 14:37:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:29

If frequency is Other, specify

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 23 Apr 2021 09:15:47 |
| User signature succeeded. | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User entered empty.       | (b) (4)<br>Lalicia Roman (b) (4) | 16 Sep 2020 14:37:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:29

[Route of administration](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 23 Apr 2021 09:15:47 |
| User signature succeeded.  | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User entered 'Oral (ORAL)' | (b) (4)<br>Lalicia Roman (b) (4) | 16 Sep 2020 14:37:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:29

If route of administration is Other, specify

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 23 Apr 2021 09:15:47 |
| User signature succeeded. | Judith Martin (b) (4)                       | 19 Feb 2021 14:46:50 |
| User entered empty.       | (b) (4)<br>Lalicia Roman (b) (4)<br>(b) (4) | 16 Sep 2020 14:37:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 23 Apr 2021 09:15:47 |
| User signature succeeded.                                      | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
| User entered '10 Sep 2020' reason for change: Data Entry Error | (b) (4)               |                      |
|  | Lalicia Roman (b) (4) | 16 Sep 2020 14:38:03 |
| User entered '9 Sep 2020'                                      | (b) (4)               |                      |
|  | Lalicia Roman (b) (4) | 16 Sep 2020 14:37:25 |
|  | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:29

[Start date completely unknown](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 23 Apr 2021 09:15:47 |
| User signature succeeded. | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User entered '0'          | (b) (4)<br>Lalicia Roman (b) (4) | 16 Sep 2020 14:37:25 |



**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:58:29**

[Ongoing?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 23 Apr 2021 09:15:47 |
| User signature succeeded. | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User entered 'No (N)'     | (b) (4)<br>Lalicia Roman (b) (4) | 16 Sep 2020 14:37:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 23 Apr 2021 09:15:47 |
| User signature succeeded.                                      | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
| User entered '17 Sep 2020' reason for change: Data Entry Error | Emily Carney (b) (4)  | 28 Oct 2020 19:10:40 |
| User entered '16 Sep 2020' reason for change: Data Entry Error | Emily Carney (b) (4)  | 28 Oct 2020 19:09:14 |
| User entered '15 Sep 2020' reason for change: Data Entry Error | Lalicia Roman (b) (4) | 16 Sep 2020 14:38:03 |
| User entered '11 Sep 2020'                                     | Lalicia Roman (b) (4) | 16 Sep 2020 14:37:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:29

Was this medication taken for solicited event?

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 23 Apr 2021 09:15:47 |
| User signature succeeded.   | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).              | (b) (4)<br>(b) (4), (b) (6)      | 18 Nov 2020 13:37:01 |
| Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'Updated ' (Site from DM). | Emily Carney (b) (4)<br>(b) (4)  | 11 Nov 2020 16:27:22 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | Emily Carney (b) (4)<br>(b) (4)  | 11 Nov 2020 16:27:01 |
| User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).              | (b) (4), (b) (6)                 | 10 Nov 2020 02:11:51 |
| User entered 'No (N)'   | Lalicia Roman (b) (4)<br>(b) (4) | 16 Sep 2020 14:37:25 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:58:29**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 23 Apr 2021 09:15:47 |
| User entered empty. | System           | 16 Sep 2020 14:37:25 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 23 Apr 2021 09:15:47 |
| User entered empty. | System           | 16 Sep 2020 14:37:25 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 23 Apr 2021 09:15:47 |
| User entered empty. | System           | 16 Sep 2020 14:37:25 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:29

Name of Medication

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User signature succeeded.   | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User closed query 'Per DM CLR: Con Med AMOXICILLIN-CLAVULANATE was added/changed on 7 OCT 2020 . Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6)      | 15 Dec 2020 10:32:18 |
| Query 'Per DM CLR: Con Med AMOXICILLIN-CLAVULANATE was added/changed on 7 OCT 2020 . Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'Participant has chronic sinusitis. Participant did not indicate a worsening or exacerbation of the condition.' (Site from DM). | Lalicia Roman (b) (4)<br>(b) (4) | 03 Dec 2020 19:57:23 |
| User opened query 'Per DM CLR: Con Med AMOXICILLIN-CLAVULANATE was added/changed on 7 OCT 2020 . Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).   | (b) (4), (b) (6)                 | 30 Nov 2020 20:17:02 |
| 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;CLAVULANIC ACID - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)  | 07 Oct 2020 20:12:58 |
| 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)  | 07 Oct 2020 20:12:58 |
| Data point term sent to Coder   | System                           | 07 Oct 2020 19:23:33 |
| User entered 'amoxicillin-clavulanate'  | Jennifer Nagg (b) (4)<br>(b) (4) | 07 Oct 2020 19:22:49 |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2654 of 2786

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:29

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Jennifer Nagg (b) (4) | 07 Oct 2020 19:22:49 |
|                           | (b) (4)               |                      |



**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:58:29**

[Indication](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User entered 'sinusitis'  | (b) (4)<br>Jennifer Nagg (b) (4) | 07 Oct 2020 19:22:49 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:29

[Dose per administration](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User entered '875/125'    | (b) (4)<br>Jennifer Nagg (b) (4) | 07 Oct 2020 19:22:49 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:29

[Dose unit](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
|                           | (b) (4)               |                      |
| User entered 'mg (mg)'    | Jennifer Nagg (b) (4) | 07 Oct 2020 19:22:49 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:29

If dose unit is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
|                           | (b) (4)               |                      |
| User entered empty.       | Jennifer Nagg (b) (4) | 07 Oct 2020 19:22:49 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:29

[Frequency](#)

| Audit                            | User                             | Time (GMT)           |
|----------------------------------|----------------------------------|----------------------|
| User signature succeeded.        | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User entered 'twice daily (BID)' | (b) (4)<br>Jennifer Nagg (b) (4) | 07 Oct 2020 19:22:49 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:29

If frequency is Other, specify

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 07 Oct 2020 19:22:49 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:58:29**

[Route of administration](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User entered 'Oral (ORAL)' | (b) (4)<br>Jennifer Nagg (b) (4) | 07 Oct 2020 19:22:49 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:58:29**

If route of administration is Other, specify

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 07 Oct 2020 19:22:49 |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
|                           | (b) (4)               |                      |
| User entered '7 Oct 2020' | Jennifer Nagg (b) (4) | 07 Oct 2020 19:22:49 |
|                           | (b) (4)               |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:29

[Start date completely unknown](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User entered '0'          | (b) (4)<br>Jennifer Nagg (b) (4) | 07 Oct 2020 19:22:49 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:58:29**

[Ongoing?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User entered 'Yes (Y)'    | (b) (4)<br>Jennifer Nagg (b) (4) | 07 Oct 2020 19:22:49 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User entered empty.       | (b) (4)<br>Jennifer Nagg (b) (4) | 07 Oct 2020 19:22:49 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:29

[Was this medication taken for solicited event?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)            | 19 Feb 2021 14:46:50 |
| User entered 'No (N)'     | (b) (4)<br>Jennifer Nagg (b) (4) | 07 Oct 2020 19:22:49 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:58:29**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 07 Oct 2020 19:22:49 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Oct 2020 19:22:49 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 07 Oct 2020 19:22:49 |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:29

[Name of Medication](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 23 Apr 2021 05:08:55 |
| User signature succeeded.   | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
| 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)  | 09 Nov 2020 18:38:34 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)  | 09 Nov 2020 18:38:34 |
| Data point term sent to Coder   | System                | 09 Nov 2020 18:37:24 |
| User entered 'Flu vaccine'  | Emily Carney (b) (4)  | 09 Nov 2020 18:37:22 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:29

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 23 Apr 2021 05:08:55 |
| User signature succeeded. | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
| User entered 'Yes (Y)'    | Emily Carney (b) (4)  | 09 Nov 2020 18:37:22 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:29

[Indication](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 23 Apr 2021 05:08:55 |
| User signature succeeded.                  | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
| User entered 'Prevent influenza infection' | Emily Carney (b) (4)  | 09 Nov 2020 18:37:22 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:29

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 23 Apr 2021 05:08:55 |
| User signature succeeded. | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
| User entered 'Unk'        | Emily Carney (b) (4)  | 09 Nov 2020 18:37:22 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:29

[Dose unit](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 23 Apr 2021 05:08:55 |
| User signature succeeded. | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
| User entered 'mL (mL)'    | Emily Carney (b) (4)  | 09 Nov 2020 18:37:22 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:29

If dose unit is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 23 Apr 2021 05:08:55 |
| User signature succeeded. | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
| User entered empty.       | Emily Carney (b) (4)  | 09 Nov 2020 18:37:22 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:29

[Frequency](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 23 Apr 2021 05:08:55 |
| User signature succeeded.  | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
| User entered 'once (ONCE)' | Emily Carney (b) (4)  | 09 Nov 2020 18:37:22 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:29

[If frequency is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 23 Apr 2021 05:08:55 |
| User signature succeeded. | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
| User entered empty.       | Emily Carney (b) (4)  | 09 Nov 2020 18:37:22 |



**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:58:29**

[Route of administration](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)      | 23 Apr 2021 05:08:55 |
| User signature succeeded.                    | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | Emily Carney (b) (4)  | 09 Nov 2020 18:37:22 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:29

If route of administration is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 23 Apr 2021 05:08:55 |
| User signature succeeded. | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
| User entered empty.       | Emily Carney (b) (4)  | 09 Nov 2020 18:37:22 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 23 Apr 2021 05:08:55 |
| User signature succeeded.  | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
| User entered '31 Oct 2020' | Emily Carney (b) (4)  | 09 Nov 2020 18:37:22 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:29

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 23 Apr 2021 05:08:55 |
| User signature succeeded. | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
| User entered '0'          | Emily Carney (b) (4)  | 09 Nov 2020 18:37:22 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:58:29**

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 23 Apr 2021 05:08:55 |
| User signature succeeded. | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
| User entered 'No (N)'     | Emily Carney (b) (4)  | 09 Nov 2020 18:37:22 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 23 Apr 2021 05:08:55 |
| User signature succeeded.  | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
| User entered '31 Oct 2020' | Emily Carney (b) (4)  | 09 Nov 2020 18:37:22 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:29

[Was this medication taken for solicited event?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 23 Apr 2021 05:08:55 |
| User signature succeeded. | Judith Martin (b) (4) | 19 Feb 2021 14:46:50 |
| User entered 'No (N)'     | Emily Carney (b) (4)  | 09 Nov 2020 18:37:22 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:58:29**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 23 Apr 2021 05:08:55 |
| User entered empty. | System           | 09 Nov 2020 18:37:22 |



**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 23 Apr 2021 05:08:55 |
| User entered empty. | System           | 09 Nov 2020 18:37:22 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 23 Apr 2021 05:08:55 |
| User entered empty. | System           | 09 Nov 2020 18:37:22 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:29

Name of Medication

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| 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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 19 Mar 2021 10:17:35 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)    | 19 Mar 2021 10:17:35 |
| User signature succeeded.   | Judith Martin (b) (4)   | 19 Feb 2021 14:46:50 |
| Data point term sent to Coder   | System                  | 18 Feb 2021 19:29:12 |
| Coding entries removed.   | Emily Carney (b) (4)    | 18 Feb 2021 19:28:37 |
| 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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 15 Dec 2020 15:03:59 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)    | 15 Dec 2020 15:03:59 |
| Data point term sent to Coder   | System                  | 15 Dec 2020 15:03:20 |
| User entered 'Pepcid'   | Emily Dougherty (b) (4) | 15 Dec 2020 15:02:35 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:29

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)   | 19 Feb 2021 14:46:50 |
|                           | (b) (4)                 |                      |
| User entered 'No (N)'     | Emily Dougherty (b) (4) | 15 Dec 2020 15:02:35 |
|                           | (b) (4)                 |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:29

[Indication](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| User closed query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.<br>' (Site from DM).             | (b) (4), (b) (6)        | 23 Feb 2021 13:14:15 |
| User signature succeeded.   | Judith Martin (b) (4)   | 19 Feb 2021 14:46:50 |
| Query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.<br>' answered with 'updated' (Site from DM). | Emily Carney (b) (4)    | 18 Feb 2021 19:28:43 |
| User entered 'Seasonal ALLERGIES' reason for change: Data Entry Error   | Emily Carney (b) (4)    | 18 Feb 2021 19:28:37 |
| User opened query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.<br>' (Site from DM).             | (b) (4), (b) (6)        | 26 Jan 2021 12:16:19 |
| User entered 'Allergies'  | Emily Dougherty (b) (4) | 15 Dec 2020 15:02:35 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:58:29**

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)   | 19 Feb 2021 14:46:50 |
|                           | (b) (4)                 |                      |
| User entered '20'         | Emily Dougherty (b) (4) | 15 Dec 2020 15:02:35 |
|                           | (b) (4)                 |                      |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:58:29**

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)   | 19 Feb 2021 14:46:50 |
|                           | (b) (4)                 |                      |
| User entered 'mg (mg)'    | Emily Dougherty (b) (4) | 15 Dec 2020 15:02:35 |
|                           | (b) (4)                 |                      |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:58:29**

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)   | 19 Feb 2021 14:46:50 |
|                           | (b) (4)                 |                      |
| User entered empty.       | Emily Dougherty (b) (4) | 15 Dec 2020 15:02:35 |
|                           | (b) (4)                 |                      |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:29

[Frequency](#)

| Audit                            | User                    | Time (GMT)           |
|----------------------------------|-------------------------|----------------------|
| User signature succeeded.        | Judith Martin (b) (4)   | 19 Feb 2021 14:46:50 |
| User entered 'twice daily (BID)' | Emily Dougherty (b) (4) | 15 Dec 2020 15:02:35 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:58:29**

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)   | 19 Feb 2021 14:46:50 |
|                           | (b) (4)                 |                      |
| User entered empty.       | Emily Dougherty (b) (4) | 15 Dec 2020 15:02:35 |
|                           | (b) (4)                 |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:29

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)   | 19 Feb 2021 14:46:50 |
|                            | (b) (4)                 |                      |
| User entered 'Oral (ORAL)' | Emily Dougherty (b) (4) | 15 Dec 2020 15:02:35 |
|                            | (b) (4)                 |                      |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:58:29**

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)   | 19 Feb 2021 14:46:50 |
|                           | (b) (4)                 |                      |
| User entered empty.       | Emily Dougherty (b) (4) | 15 Dec 2020 15:02:35 |
|                           | (b) (4)                 |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)   | 19 Feb 2021 14:46:50 |
|                            | (b) (4)                 |                      |
| User entered '24 Nov 2020' | Emily Dougherty (b) (4) | 15 Dec 2020 15:02:35 |
|                            | (b) (4)                 |                      |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:58:29**

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)   | 19 Feb 2021 14:46:50 |
|                           | (b) (4)                 |                      |
| User entered '0'          | Emily Dougherty (b) (4) | 15 Dec 2020 15:02:35 |
|                           | (b) (4)                 |                      |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:58:29**

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)   | 19 Feb 2021 14:46:50 |
|                           | (b) (4)                 |                      |
| User entered 'Yes (Y)'    | Emily Dougherty (b) (4) | 15 Dec 2020 15:02:35 |
|                           | (b) (4)                 |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)   | 19 Feb 2021 14:46:50 |
|                           | (b) (4)                 |                      |
| User entered empty.       | Emily Dougherty (b) (4) | 15 Dec 2020 15:02:35 |
|                           | (b) (4)                 |                      |



US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:58:29**

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)   | 19 Feb 2021 14:46:50 |
| User entered 'No (N)'     | Emily Dougherty (b) (4) | 15 Dec 2020 15:02:35 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:58:29**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 15 Dec 2020 15:02:35 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Dec 2020 15:02:35 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 15 Dec 2020 15:02:35 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:58:29

[Name of Medication](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)    | 08 Apr 2021 18:40:53 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)     | 08 Apr 2021 18:23:53 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)     | 08 Apr 2021 18:23:53 |
| Data point term sent to Coder  | System                   | 08 Apr 2021 18:22:42 |
| User entered 'Miralax'   | Melissa Andrasko (b) (4) | 08 Apr 2021 18:21:50 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:58:29

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)    | 08 Apr 2021 18:40:53 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Melissa Andrasko (b) (4) | 08 Apr 2021 18:21:50 |
|                           | (b) (4)                  |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:58:29

[Indication](#)

| Audit  | User   | Time (GMT)           |
|--|--|----------------------|
| User signature succeeded.                                | Judith Martin (b) (4)                          | 08 Apr 2021 18:40:53 |
| User entered 'prevention of post-operative constipation' | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 08 Apr 2021 18:21:50 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:58:29

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)    | 08 Apr 2021 18:40:53 |
|                           | (b) (4)                  |                      |
| User entered '17'         | Melissa Andrasko (b) (4) | 08 Apr 2021 18:21:50 |
|                           | (b) (4)                  |                      |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:58:29

[Dose unit](#)

| Audit                        | User                     | Time (GMT)           |
|------------------------------|--------------------------|----------------------|
| User signature succeeded.    | Judith Martin (b) (4)    | 08 Apr 2021 18:40:53 |
|                              | (b) (4)                  |                      |
| User entered 'Other (OTHER)' | Melissa Andrasko (b) (4) | 08 Apr 2021 18:21:50 |
|                              | (b) (4)                  |                      |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:58:29**

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)    | 08 Apr 2021 18:40:53 |
|                           | (b) (4)                  |                      |
| User entered 'grams'      | Melissa Andrasko (b) (4) | 08 Apr 2021 18:21:50 |
|                           | (b) (4)                  |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:58:29

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded.      | Judith Martin (b) (4)    | 08 Apr 2021 18:40:53 |
|                                | (b) (4)                  |                      |
| User entered 'once daily (QD)' | Melissa Andrasko (b) (4) | 08 Apr 2021 18:21:50 |
|                                | (b) (4)                  |                      |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:58:29**

[If frequency is Other, specify](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)    | 08 Apr 2021 18:40:53 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Melissa Andrasko (b) (4) | 08 Apr 2021 18:21:50 |
|                           | (b) (4)                  |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:58:29

[Route of administration](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)                          | 08 Apr 2021 18:40:53 |
| User entered 'Oral (ORAL)' | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 08 Apr 2021 18:21:50 |

US3802168

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:58:29**

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)    | 08 Apr 2021 18:40:53 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Melissa Andrasko (b) (4) | 08 Apr 2021 18:21:50 |
|                           | (b) (4)                  |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:58:29

Start date (dd MMM yyyy)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)    | 08 Apr 2021 18:40:53 |
|                           | (b) (4)                  |                      |
| User entered '1 Apr 2021' | Melissa Andrasko (b) (4) | 08 Apr 2021 18:21:50 |
|                           | (b) (4)                  |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:58:29

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)    | 08 Apr 2021 18:40:53 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Melissa Andrasko (b) (4) | 08 Apr 2021 18:21:50 |
|                           | (b) (4)                  |                      |



US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:58:29

[Ongoing?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 08 Apr 2021 18:40:53 |
| User entered 'No (N)'     | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 08 Apr 2021 18:21:50 |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:58:29

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)    | 08 Apr 2021 18:40:53 |
|                           | (b) (4)                  |                      |
| User entered '7 Apr 2021' | Melissa Andrasko (b) (4) | 08 Apr 2021 18:21:50 |
|                           | (b) (4)                  |                      |

US3802168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:58:29

[Was this medication taken for solicited event?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Judith Martin (b) (4)                          | 08 Apr 2021 18:40:53 |
| User entered 'No (N)'     | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 08 Apr 2021 18:21:50 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:58:29**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Apr 2021 18:21:50 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Apr 2021 18:21:50 |

**US3802168**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:58:29**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 08 Apr 2021 18:21:50 |

US3802168

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:58:29

[Were any concomitant procedures performed?](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 03 May 2021 05:57:48 |
| User signature succeeded.                                  | Judith Martin (b) (4)               | 13 Feb 2021 12:34:03 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4)<br>Melissa Andrasko (b) (4) | 10 Feb 2021 13:37:03 |
| User entered 'No (N)'                                      | Emily Carney (b) (4)                | 08 Feb 2021 14:01:55 |

US3802168

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:58:29

Procedure/Surgery date (dd MMM yyyy)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 01 May 2021 15:01:31 |
| User signature succeeded.   | Judith Martin (b) (4)    | 13 Feb 2021 12:34:03 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4)                  |                      |
| User entered '03 Feb 2021' reason for change: Data Entry Error                          | System                   | 10 Feb 2021 15:29:28 |
|   | Melissa Andrasko (b) (4) | 10 Feb 2021 15:29:28 |
|   | (b) (4)                  |                      |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System                   | 10 Feb 2021 13:40:45 |
| User entered ' Feb 2021' (non-conformant).  | Melissa Andrasko (b) (4) | 10 Feb 2021 13:40:45 |
|   | (b) (4)                  |                      |



US3802168

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:58:29

[Procedure/Surgery](#)

| Audit                               | User                                | Time (GMT)           |
|-------------------------------------|-------------------------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6)                    | 01 May 2021 15:01:31 |
| User signature succeeded.           | Judith Martin (b) (4)               | 13 Feb 2021 12:34:03 |
| User entered 'Esophageal Manometry' | (b) (4)<br>Melissa Andrasko (b) (4) | 10 Feb 2021 13:40:45 |

US3802168

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:58:29

[Indication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 01 May 2021 15:01:31 |
| User closed query 'Per CDM: ESOPHAGEAL MANOMETRY indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you.' (Site from DM).   |                                     | 17 Mar 2021 08:38:07 |
| Query 'Per CDM: ESOPHAGEAL MANOMETRY indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you.' answered with 'This test was performed due to frequent heart burn which is already recorded in the MH.' (Site from DM). | Emily Carney (b) (4)<br>(b) (4)     | 12 Mar 2021 15:42:55 |
| User opened query 'Per CDM: ESOPHAGEAL MANOMETRY indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you.' (Site from DM).   | (b) (4), (b) (6)                    | 12 Mar 2021 09:42:09 |
| User signature succeeded.  | Judith Martin (b) (4)<br>(b) (4)    | 13 Feb 2021 12:34:03 |
| User entered 'Medical History (MH)'  | Melissa Andrasko (b) (4)<br>(b) (4) | 10 Feb 2021 13:40:45 |

US3802168

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:58:29

If indication is Other, specify

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 01 May 2021 15:01:31 |
| User signature succeeded. | Judith Martin (b) (4)               | 13 Feb 2021 12:34:03 |
| User entered empty.       | (b) (4)<br>Melissa Andrasko (b) (4) | 10 Feb 2021 13:40:45 |

US3802168

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:58:29

Procedure/Surgery date (*dd MMM yyyy*)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| User signature succeeded.  | Judith Martin (b) (4)                          | 08 Apr 2021 18:40:53 |
| User entered '30 Mar 2021' | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 08 Apr 2021 18:24:38 |

US3802168

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:58:29

[Procedure/Surgery](#)

| Audit   | User   | Time (GMT)           |
|---|--|----------------------|
| User signature succeeded.   | Judith Martin (b) (4)                          | 08 Apr 2021 18:40:53 |
| User entered 'exploratory laparotomy, excision of perihepatic mass' | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 08 Apr 2021 18:24:38 |

US3802168

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:58:29

[Indication](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--|----------------------|
| User signature succeeded.           | Judith Martin (b) (4)                          | 08 Apr 2021 18:40:53 |
| User entered 'Medical History (MH)' | (b) (4)<br>Melissa Andrasko (b) (4)<br>(b) (4) | 08 Apr 2021 18:24:38 |

US3802168

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:58:29

If indication is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)    | 08 Apr 2021 18:40:53 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Melissa Andrasko (b) (4) | 08 Apr 2021 18:24:38 |
|                           | (b) (4)                  |                      |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:06 |
| User entered<br>'USA-US098-2021-MRNA-1273-P301000004' | System                      | 20 Apr 2021 18:14:35 |



**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'Yes (Y)'    | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'No (N)'     | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'No (N)'     | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'Yes (Y)'    | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'No (N)'     | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'No (N)'     | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'No (N)'     | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'Judith'     | System                      | 20 Apr 2021 18:14:35 |



US3802168

Folder: SAE USA-US098-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:29

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'Martin'     | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Site Address: Street](#)

| Audit                         | User                        | Time (GMT)           |
|-------------------------------|-----------------------------|----------------------|
| User signature succeeded.     | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.          | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered '3420 Fifth Ave' | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Site Address: City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(v) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'Pittsburgh' | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'PA'         | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered '15213'      | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Investigator Country](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)      | 29 Apr 2021 15:20:50 |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 21 Apr 2021 18:50:39 |
|                           | (b) (4)               |                      |
| User entered 'US'         | System                | 20 Apr 2021 18:22:21 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 29 Apr 2021 15:21:11 |
| User entered '1' | System | 20 Apr 2021 18:22:21 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:06 |
| User entered<br>'USA-US098-2021-MRNA-1273-P301000004' | System                      | 20 Apr 2021 18:14:35 |



**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(v) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'Yes (Y)'    | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'No (N)'     | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(v) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'No (N)'     | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'Yes (Y)'    | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(d) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'No (N)'     | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'No (N)'     | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'No (N)'     | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'Judith'     | System                      | 20 Apr 2021 18:14:35 |



**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'Martin'     | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Site Address: Street](#)

| Audit                         | User                        | Time (GMT)           |
|-------------------------------|-----------------------------|----------------------|
| User signature succeeded.     | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.          | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered '3420 Fifth Ave' | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Site Address: City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'Pittsburgh' | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'PA'         | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered '15213'      | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Investigator Country](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)      | 29 Apr 2021 15:20:50 |
| User signature succeeded. | Judith Martin (b) (4) | 21 Apr 2021 18:50:39 |
| User entered 'US'         | (b) (4)<br>System     | 20 Apr 2021 18:22:21 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 29 Apr 2021 15:21:11 |
| User entered '1' | System | 20 Apr 2021 18:22:21 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:58:29**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| User signature succeeded.        | Judith Martin (b) (4) | 21 Apr 2021 18:50:39 |
| User entered '20/Apr/2021 14:22' | (b) (4)<br>System     | 20 Apr 2021 18:22:21 |



US3802168

Folder: SAE USA-US098-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:58:29

**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.**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)      | 29 Apr 2021 15:20:50 |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 21 Apr 2021 18:50:39 |
|                           | (b) (4)               |                      |
| User entered 'I'          | (b) (4), (b) (6)      | 20 Apr 2021 18:22:21 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:06 |
| User entered<br>'USA-US098-2021-MRNA-1273-P301000004' | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'Yes (Y)'    | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(v) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'No (N)'     | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'No (N)'     | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(c) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'Yes (Y)'    | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'No (N)'     | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'No (N)'     | System                      | 20 Apr 2021 18:14:35 |



US3802168

Folder: SAE USA-US098-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:29

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'No (N)'     | System                      | 20 Apr 2021 18:14:35 |

US3802168

Folder: SAE USA-US098-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:29

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'Judith'     | System                      | 20 Apr 2021 18:14:35 |

US3802168

Folder: SAE USA-US098-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:29

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'Martin'     | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Site Address: Street](#)

| Audit                         | User                        | Time (GMT)           |
|-------------------------------|-----------------------------|----------------------|
| User signature succeeded.     | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.          | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered '3420 Fifth Ave' | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Site Address: City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(d) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'Pittsburgh' | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered 'PA'         | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 21 Apr 2021 18:50:39 |
| Reviewed for Safety.      | (b) (4)<br>(v) (4), (b) (6) | 20 Apr 2021 18:22:13 |
| User entered '15213'      | System                      | 20 Apr 2021 18:14:35 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[Investigator Country](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)      | 29 Apr 2021 15:20:50 |
|                           |                       |                      |
| User signature succeeded. | Judith Martin (b) (4) | 21 Apr 2021 18:50:39 |
|                           | (b) (4)               |                      |
| User entered 'US'         | System                | 20 Apr 2021 18:22:21 |



**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 29 Apr 2021 15:21:11 |
| User entered '1' | System | 20 Apr 2021 18:22:21 |

**US3802168**

**Folder: SAE USA-US098-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:58:29**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| User signature succeeded.        | Judith Martin (b) (4) | 29 Apr 2021 16:29:31 |
| User entered '29/Apr/2021 11:21' | (b) (4)<br>System     | 29 Apr 2021 15:21:11 |

US3802168

Folder: SAE USA-US098-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:58:29

**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.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Judith Martin (b) (4)       | 29 Apr 2021 16:29:31 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 29 Apr 2021 15:21:11 |